Analysis
As of: Mar 12, 2009

Joseph Blunt, Sr. and Margaret Blunt, Plaintiffs-Appellants-Petitioners, State of Wisconsin Department of Health and Family Services, Subrogated-Plaintiff, v. Medtronic, Inc., Defendant-Respondent.

No. 2006AP1506

SUPREME COURT OF WISCONSIN

2009 WI 16*; *2009 Wisc. LEXIS 11

October 7, 2008, Argued
February 17, 2009, Filed

NOTICE:

THIS OPINION IS SUBJECT TO FURTHER EDITING AND MODIFICATION. THE FINAL VERSION WILL APPEAR IN THE BOUND VOLUME OF THE OFFICIAL REPORTS.

PRIOR HISTORY: [**1]

COURT: Circuit. COUNTY: Milwaukee. JUDGE: Richard J. Sankovitz. (L.C. No. 2005CV3879). REVIEW of a decision of the Court of Appeals.

Blunt v. Medtronic, Inc., 2007 WI App 191, 305 Wis. 2d 354, 738 N.W.2d 143, 2007 Wisc. App. LEXIS 667 (2007)

DISPOSITION: Affirmed.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiffs, a patient and his wife, brought an action against defendant defibrillator manufacturer in the circuit court, alleging negligence, strict liability and loss of consortium. The manufacturer filed a motion for summary judgment, arguing that the claims were expressly preempted by *21 U.S.C.S. § 360k(a)*. The circuit court granted summary judgment to the manufacturer. The Wisconsin Court of Appeals affirmed, and the patient appealed.

OVERVIEW: In 2002, the manufacturer received Food and Drug Administration (FDA) premarket approval to market and distribute a defibrillator. Subsequent to this approval, the manufacturer became aware of a potential shorting problem and submitted a premarket approval supplemental application containing three design changes. However, the manufacturer continued to sell the original defibrillator, and an original one was surgically implanted in the patient. When he discovered the shorting problem, he had it removed, leading to complications and his lawsuit against the manufacturer. The court held that the defibrillator was approved under the premarket approval process, *21 U.S.C.S. § 360e*, and therefore met the federal "requirement" specific to that device, pursuant to *21 U.S.C.S. § 360k(a)*. The patient's common law claims constituted state requirements that were "different from, or in addition to," the federal requirement, within the meaning of *§ 360k*, and were therefore preempted. The supplemental approval did not revoke the original approval.

OUTCOME: The court affirmed the grant of summary judgment to the manufacturer.

CORE TERMS: premarket, defibrillator, medical device, supplemental, federal requirement, preempted, preemption, manufacturer's, effectiveness, state tort, device-specific, tort claims, airbag', implied preemption, approval process, federal law, state law, state requirements, strict liability, consortium, law claims, express preemption, labeling, marketed, preempt, scientists, shorting, safety standard, oral argument, withdraw

LexisNexis(R) Headnotes

Healthcare Law > Treatment > Medical Devices > Premarket Approval

[HN1] "Supplemental premarket approval," or "supplemental approval," is Food and Drug Administration (FDA) approval for a device that is similar to a device that previously has received premarket approval, where the manufacturer changes the design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. *21 U.S.C.S. § 360e(d)(6)(A)(i)*. In order to obtain supplemental approval, the manufacturer must submit, and the FDA must approve, an application to be evaluated under largely the same criteria as an initial application for premarket approval. *21 U.S.C.S. § 360e(d)(6)*; *21 C.F.R. § 814.39(c)*.

Healthcare Law > Treatment > Medical Devices > Premarket Approval

[HN2] Under the Medical Device Amendments, a defibrillator is a Class III device, subject to the Food and Drug Administration's (FDA) strictest regulation and oversight, because it is for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health. *21 U.S.C.S. § 360c(a)(1)(C)*. With some exceptions, a Class III device may not be marketed or distributed without premarket approval from the FDA. The procedures for obtaining premarket approval are outlined in *21 U.S.C.S. § 360e*.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
[HN3] Premarket approval from the Food and Drug Administration (FDA) is a rigorous process. A manufacturer must submit what is typically a multivolume application. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling. *21 U.S.C.S. § 360e(c)(1)*. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, *21 C.F.R. § 814.44(a) (2007)*, and may request additional data from the manufacturer, *§ 360e(c)(1)(G)*.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
[HN4] Once a medical device has received premarket approval, the Medical Device Amendments forbid the manufacturer to make, without Food and Drug Administration (FDA) permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. *21 U.S.C.S. § 360e(d)(6)(A)(i)*. If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. *Section 360e(d)(6)*; *21 C.F.R. § 814.39(c)*.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
[HN5] After premarket approval by the Food and Drug Administration (FDA), medical devices are subject to reporting requirements. *21 U.S.C.S. § 360i*. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, *21 C.F.R. § 814.84(b)(2)*, and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, *21 C.F.R. § 803.50(a)*. The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. *21 U.S.C.S. §§ 360e(e)(1)*; 360h(e).

Healthcare Law > Treatment > Medical Devices > Premarket Approval
[HN6] A manufacturer need not obtain premarket approval for a new medical device if it is "substantially equivalent" to a device that is exempt from premarket approval. *21 U.S.C.S. § 360c(f)(1)(A)*.

Healthcare Law > Treatment > Medical Devices > Classification & Regulation
Torts > Procedure > Preemption > Express Preemption
[HN7] See *21 U.S.C.S. § 360k(a)*.

Civil Procedure > Summary Judgment > Appellate Review > Standards of Review
Civil Procedure > Appeals > Standards of Review > De Novo Review
[HN8] An appellate court reviews a summary judgment decision independently, employing the same methodology as the circuit court.

Civil Procedure > Appeals > Standards of Review > De Novo Review
Governments > Legislation > Interpretation
[HN9] An appellate court interprets statutes independently of the circuit court and court of appeals, but benefitting from their analyses.

Civil Procedure > Appeals > Standards of Review > De Novo Review
Torts > Procedure > Preemption > Express Preemption
[HN10] Whether federal preemption applies is a question of federal law that an appellate court reviews independently.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
[HN11] Device-specific premarket approval of a Class III medical device constitutes a federal "requirement" within the meaning of *21 U.S.C.S. § 360k(a)*. Premarket approval imposes "requirements" under the Medical Device Amendments. Unlike general labeling duties, premarket approval is specific to individual devices. Premarket approval is federal safety review. The Food and Drug Administration (FDA) may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness. The FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

Torts > Procedure > Preemption > Express Preemption
[HN12] Absent other indication, reference to a State's "requirements" in the preemption statute of the Medical Device Amendments, *21 U.S.C.S. § 360k*, includes its common-law duties. Common-law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a state-law obligation. While the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
Torts > Procedure > Preemption > Express Preemption
[HN13] State tort claims based on injuries caused by a Class III medical device that was granted device-specific premarket approval by the Food and Drug Administration may be preempted by *21 U.S.C.S. § 360k(a)*. State tort claims based on such medical devices are preempted when they relate to the safety or effectiveness of the device. In addition, such claims must be different from, or in addition to, the federal requirement of premarket approval.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
Torts > Procedure > Preemption > Express Preemption
[HN14] Common-law causes of action for negligence and strict liability do impose requirements and are preempted by federal requirements specific to a medical device.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
Torts > Procedure > Preemption > Express Preemption
[HN15] Congress has expressly preempted state law requirements that are different from or in addition to the federal requirement of device-specific premarket approval for Class III medical devices. *21 U.S.C.S. § 360k(a)*.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
Torts > Procedure > Preemption > Express Preemption
[HN16] The Medical Device Amendments to the Food, Drug & Cosmetic Act, *21 U.S.C.S. § 360k*, provide that no State may establish or continue in effect with respect to a device any requirement relating to safety or effectiveness that is different from, or in addition to, federal requirements.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
[HN17] The Food and Drug Administration has the power to withdraw premarket approval or to recall a device to which it has given premarket approval. *21 U.S.C.S. §§ 360e(e)(1)*; 360h(e).

Healthcare Law > Treatment > Medical Devices > Premarket Approval
[HN18] Under the comprehensive scheme that Congress has enacted, withdrawal of a manufacturer's right to market its premarket-approved devices is accomplished through affirmative acts of the Food and Drug Administration (FDA). There is nothing to suggest that premarket approval ceases without FDA action. For example, federal law directs that for the withdrawal or temporary suspension of premarket approval, due notice and opportunity for informal hearing must be given. *21 U.S.C.S. § 360e(e)*1. The FDA has express authority to recall premarket approved Class III medical devices when the FDA finds there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death. *21 U.S.C.S. § 360h(e)(1)*.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
Torts > Procedure > Preemption > Express Preemption
[HN19] The federal government's approval of a supplemental medical device does not affect the approval of the original device. Accordingly, a state tort claim will be preempted by the original federal approval.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
[HN20] A manufacturer often may have a number of different supplemental premarket-approved devices on the market at any given time.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
[HN21] Supplemental premarket approvals do not necessarily occur because newer versions are more safe than predecessor versions, but rather, because the law requires premarket approval for most changes in design. For example, under *21 C.F.R. § 814.39(a)*, supplemental approval must be obtained when the proposed changes allow for a new use of the device, affect the labeling or packaging of the device, or require a different facility to process the device. Therefore, when a manufacturer obtains supplemental approval for a medical device, absent further action by the Food and Drug Administration (FDA), prior approvals of the device remain valid and accordingly the federal requirement established by premarket approval is ongoing.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
Torts > Procedure > Preemption > Express Preemption
[HN22] Through the federal requirement of device-specific premarket approval, the Food and Drug Administration (FDA) requires a device to be made with almost no deviations from the specifications in its approval application. That is, "requirement" under *21 U.S.C.S. § 360k(a)* refers to safety and efficacy federal requirements that a manufacturer must satisfy before its product may be approved and marketed. State tort claims based on the safety of a device also are "requirements" under *§ 360k*; however, they are state requirements, rather than federal requirements.

Healthcare Law > Treatment > Medical Devices > Premarket Approval
Torts > Procedure > Preemption > Express Preemption
[HN23] The term "requirement" in *21 U.S.C.S. § 360k* encompasses both federally mandated criteria for medical devices before they can be marketed and sold (a federal requirement) and state tort claims that require manufacturers to design their devices with a certain level of safety (a state requirement) before they are marketed and sold in order to avoid tort liability. However, the term, "requirement," does not mean that a manufacturer is required to sell one particular approved device among several devices that have been given device-specific premarket approval. To the contrary, premarket approval does not require the manufacturer to sell any premarket approved medical devices at all.

COUNSEL: For the plaintiffs-appellants-petitioners briefs were filed by John C. Cabaniss, Thomas Armstrong, and von Briesen & Roper, S.C., Milwaukee, and oral argument by John C. Cabaniss.

For the defendant-respondent there was a brief by Michael K. Brown, Lisa M. Baird, and Reed Smith LLP, Los Angeles, Cal., and Robert H. Friebert and Friebert, Finerty & St. John S.C., Milwaukee, and oral argument by Michael K. Brown.

An amicus curiae brief was filed by Stephanie A. Scharf, David W. Austin, and Schoeman, Updike, Kaufman & Scharf, Chicago, Ill., and Coleen D. Ball, Wauwatosa, on behalf of The Product Liability Advisory Council.

An amicus curiae brief was filed by Anne Berleman Kearney, Joseph D. Kearney, and Appellate Consulting Group, Milwaukee, on behalf of the Wisconsin Manufacturers & Commerce.

An amicus curiae brief was filed by William C. Gleisner, III and the Law Offices of William C. Gleisner, Milwaukee, and Rhonda L. Lanford and Habush Habush & Rottier S.C., Madison, on behalf of the Wisconsin Association for Justice, and oral argument by William [**2] C. Gleisner, III.

JUDGES: BRADLEY, J., concurs (opinion filed). ABRAHAMSON, C.J., joins concurrence.

OPINION BY: PATIENCE DRAKE ROGGENSACK

OPINION

[*P1] PATIENCE DRAKE ROGGENSACK, J. We review a decision of the court of appeals [1] affirming the circuit court's decision [2] granting summary judgment in favor of Medtronic, Inc. Both the circuit court and the court of appeals agreed that the express preemption provision of the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, specifically *21 U.S.C. § 360k(a) (2000)*, [3] preempted the negligence, strict liability and loss of consortium claims asserted by the plaintiffs, Joseph and Margaret Blunt (the Blunts).

1 *Blunt v. Medtronic, Inc., 2007 WI App 191, 305 Wis. 2d 354, 738 N.W.2d 143*.
2 The Honorable Richard J. Sankovitz of Milwaukee County presided.
3 All further references to the United States Code are to the 2000 version unless otherwise noted.

[*P2] Our decision in this case turns on whether the Blunts' state law tort claims are preempted by federal law. In order to decide this issue, we must answer three questions. The first is whether Medtronic's Marquis 7230 implantable cardioverter defibrillator (the Marquis 7230 defibrillator), which was approved under [**3] the Food and Drug Administration's (FDA) premarket approval process, *21 U.S.C. § 360e*, met the federal "requirement" specific to that device, pursuant to *21 U.S.C. § 360k(a)*, when it received premarket approval. The second question is whether the Blunts' common law claims, which allege negligence, strict liability and loss of consortium, constitute state requirements that are "different from, or in addition to," the federal requirement. The third question is whether the preemption analysis of *Riegel v. Medtronic, Inc., U.S., 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008)*, applies to claims against the Marquis 7230 defibrillator, even though supplemental premarket approval [4] was given to a later defibrillator. Because we conclude that the United States Supreme Court's decision in Riegel provides definitive direction on these questions, [5] we answer all of them in the affirmative. We therefore conclude that *§ 360k(a)* preempts the Blunts' claims. Accordingly, we affirm the decision of the court of appeals.

4 [HN1] "Supplemental premarket approval," or "supplemental approval," is FDA approval for a device that is similar to a device that previously has received premarket approval, where the manufacturer changes the "design [**4] specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel v. Medtronic, Inc., U.S. , 128 S. Ct. 999, 1005, 169 L. Ed. 2d 892 (2008)* (citing *21 U.S.C. § 360e(d)(6)(A)(i)*). In order to obtain "supplemental approval," the manufacturer "must submit, and the FDA must approve, an application . . . to be evaluated under largely the same criteria as an initial application" for premarket approval. Id. (citing *21 U.S.C. § 360e(d)(6)*; *21 C.F.R. § 814.39(c)*).
5 We note that when this case was presented for oral argument there were two federal preemption cases pending before the United States Supreme Court. See *Good v. Altria Group, Inc., 501 F.3d 29 (1st Cir. 2007)*, cert. granted, ___ *U.S. ___, 128 S. Ct. 1119, 169 L. Ed. 2d 846 (2008)*; *Levine v. Wyeth, 944 A.2d 179 (Vt. 2006)*, cert. granted, ___ *U.S. ___, 128 S. Ct. 1118, 169 L. Ed. 2d 845 (2008)*. Altria has since been decided. *Altria v. Good, U.S. , 129 S. Ct. 538, 172 L. Ed. 2d 398 (2008)*. Neither case is relevant to our discussion. In Altria, the Supreme Court interpreted an express preemption provision that is different from the statute interpreted in

Riegel. *Id. at 548-49*. In Levine, there is no relevant express preemption provision, [**5] rather the case turns on whether conflict preemption applies. *Levine, 944 A.2d at 184*. Neither case addresses the FDA premarket approval process at issue here.

I. BACKGROUND [6]

6 The facts related are undisputed unless otherwise noted.

[*P3] In 2002, Medtronic applied for FDA premarket approval to market and distribute its Marquis 7230 defibrillator. [HN2] Under the Medical Device Amendments, a defibrillator such as the Marquis 7230 is a Class III device, subject to the FDA's strictest regulation and oversight, because it is "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." *21 U.S.C. § 360c(a)(1)(C)*. With some exceptions, [7] a Class III device may not be marketed or distributed without premarket approval from the FDA. Id. The procedures for obtaining premarket approval are outlined in *21 U.S.C. § 360e*. In Riegel, the United States Supreme Court detailed the premarket approval process as follows:

> [HN3] Premarket approval is a "rigorous" process. A manufacturer must submit what is typically a multivolume application. It includes, among other things, full reports of all studies and investigations of the device's safety [**6] and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. [*21 U.S.C.] § 360e(c)(1)*. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, *21 CFR § 814.44(a) (2007)*, and may request additional data from the manufacturer, *§ 360e(c)(1)(G)*.
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> . . . .
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> [HN4] Once a device has received premarket approval, the [Medical Device Amendments] forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. *§ 360e(d)(6)(A)(i)*. If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria [**7] as an initial application. *§ 360e(d)(6)*; *21 CFR § 814.39(c)*.
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> [HN5] After premarket approval, the devices are subject to reporting requirements. *§ 360i*. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, *21 CFR § 814.84(b)(2)*, and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, *§ 803.50(a)*. The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. *§ 360e(e)(1)*; see also *§ 360h(e)* (recall authority).

Riegel, 128 S. Ct. at 1004-05 (some citations omitted).

7 The Medical Device Amendments grandfathered approval for certain Class III devices. For example, those devices sold before the Medical Device Amendments' effective date are not required to undergo the premarket approval process. *21 U.S.C. §§ 360c(f)(1)*, *360e(b)(1)*. In addition, [HN6] a manufacturer [**8] need not obtain premarket approval for a new device if it is "substantially equivalent" to a device that is exempt from premarket approval. *21 U.S.C. § 360c(f)(1)(A)*.

[*P4] On December 17, 2002, the FDA provided device-specific premarket approval to Medtronic for its Marquis 7230 defibrillator. Subsequent to this approval, as a result of laboratory testing, Medtronic became aware of a potential shorting problem with the defibrillator's battery. This shorting problem could cause the defibrillator's battery to rapidly discharge, leading to a potentially fatal loss of power in the device. [8]

8 The parties do not dispute that this failure rate was on the order of 1 in 10,000 and that no device failed outside of controlled testing conditions. For some perspective, consider that the FDA, on a prior occasion, had approved "a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent." *Riegel, 128 S. Ct. at 1004*.

[*P5] Medtronic submitted to the FDA a premarket approval supplemental application containing three design changes that addressed the shorting issue. On October 23, 2003, the FDA approved these changes. [9] However, [**9] at no relevant time did the FDA withdraw its approval of the original defibrillator, [10] and following the supplemental premarket approval, Medtronic continued to market and distribute the original defibrillator.

9 Both parties agree that the 2002 approval of the "original" Marquis 7230 defibrillator was itself a "supplemental" premarket approval of an earlier approved design. It appears that there were a number of earlier revisions (according to oral argument, either 23 or 29 revisions) to the device that also received premarket approvals prior to the December 17, 2002 approval of the "original" Marquis 7230. Therefore, for the sake of our discussion, we will refer to the December 17, 2002 approval as the approval of the "original" Marquis 7230, and the October 23, 2003 approval as the approval of the supplemental Marquis 7230. As the United States Supreme Court noted, "an application for supplemental premarket approval [is] evaluated under largely the same criteria as an initial application." *Riegel, 128 S. Ct. at 1005* (citing *21 U.S.C. § 360e(d)(6)*; *21 CFR § 814.39(c)*).

10 In the Blunts' briefs to this Court, they supplemented much of their factual background information with citations [**10] to *In re Medtronic, Inc., Implantable Defibrillators Litigation, 465 F. Supp. 2d 886 (D. Minn. 2006)*, which also dealt with the original Marquis 7230 defibrillator. However, the claims in that case were based on different factual allegations and legal theories than those alleged here. Furthermore, the March 16, 2006 FDA recall referenced in that case to which the Blunts refer did not occur until after Joseph Blunt's surgery.

[*P6] In May of 2004, an original Marquis 7230 defibrillator was implanted in Joseph Blunt. In February of 2005, Medtronic advised physicians of the shorting problem. Less than ten days after his physician received notice of this problem, Joseph Blunt underwent surgery to remove the device at his doctor's suggestion. However, at no time did his defibrillator malfunction.

[*P7] Following the second surgery, the Blunts sued Medtronic, alleging negligence, strict liability and loss of consortium based on the second surgery. Medtronic moved for summary judgment, arguing that the Blunts' claims were expressly preempted by *21 U.S.C. § 360k(a)*. *Section 360k(a)* is a provision of the Medical Device Amendments that provides in pertinent part:

> [HN7] [N]o State or political subdivision of a [**11] State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

[*P8] Before the circuit court and court of appeals, Medtronic argued that federal premarket approval constituted a "requirement applicable under this chapter" to the device, also known as a federal "requirement." *21 U.S.C. § 360k(a)(1)*. In addition, Medtronic argued that the Blunts' state tort claims alleging negligence and strict liability were expressly preempted by *§ 360k(a)(1)* because they constituted state requirements that were "different from, or in addition to," the federal requirement that related "to the safety or effectiveness of the device." *§ 360k(a)*. The Blunts' contentions were directly opposite Medtronic's in regard to these two issues.

[*P9] At the time the circuit court ruled on Medtronic's motion, prior to the Supreme Court's decision in Riegel, there was a split among federal appellate courts with respect [**12] to both issues. Regarding the first issue, most federal circuit court decisions had concluded that device-specific premarket approval constituted a federal requirement within the meaning of *21 U.S.C. § 360k(a)(1)*. See *Riegel v. Medtronic, Inc., 451 F.3d 104 (2d Cir. 2006)*, aff'd, *U.S. , 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008)*; *Gomez v. St. Jude Med. Daig Div. Inc., 442 F.3d 919 (5th Cir. 2006)*;

McMullen v. Medtronic, Inc., 421 F.3d 482 (7th Cir. 2005), cert. denied, *547 U.S. 1003, 126 S. Ct. 1464, 164 L. Ed. 2d 246 (2006)*; *Cupek v. Medtronic, Inc., 405 F.3d 421 (6th Cir. 2005)*, cert. denied sub nom *Knisley v. Medtronic, Inc., 546 U.S. 935, 126 S. Ct. 420, 163 L. Ed. 2d 320 (2005)*; *Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004)*; *Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001)*; *Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001)*; *Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000)*; *Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997)*. An opinion of the Eleventh Circuit was the lone exception. See *Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999)*.

[*P10] With respect to the second issue, a majority of federal circuit courts that had addressed the issue also concluded that state tort claims that relate to safety or effectiveness of the device [**13] constituted state requirements "different from, or in addition to," the federal requirement, and thereby were preempted under *21 U.S.C. § 360k(a)*. See *Riegel, 451 F.3d at 122*; *Gomez, 442 F.3d at 929-30*; *McMullen, 421 F.3d at 488-89*; *Cupek, 405 F.3d at 424*; *Horn, 376 F.3d at 176*; *Brooks, 273 F.3d at 796*; *Papike v. Tambrands Inc., 107 F.3d 737, 741 (9th Cir. 1997)*. Again, the Eleventh Circuit's decision in Goodlin was the lone exception. *Goodlin, 167 F.3d at 1378-79*.

[*P11] In its order granting Medtronic's motion for summary judgment, the circuit court analyzed these lines of cases, and concluded that the reasoning of the majority of the federal circuits was more persuasive on both issues: (1) that device-specific premarket approval constituted a federal requirement; and (2) that state tort claims based on an alleged lack of safety in a device that had received premarket approval constituted state requirements "different from, or in addition to," the federal requirement. As a result, because Medtronic's original Marquis 7230 had received device-specific premarket approval, and because the Blunts' claims sounded in negligence and strict liability based on the safety of that device, the circuit [**14] court held that their claims were preempted by *21 U.S.C. § 360k(a)*. Accordingly, the circuit court granted summary judgment to Medtronic. The court of appeals, in affirming the circuit court, essentially adopted the circuit court's reasoning. [11] *Blunt, 305 Wis. 2d 354, PP12, 16*.

11 Judge Fine dissented from the decision of the court of appeals.

[*P12] We granted review and now affirm.

II. DISCUSSION

A. Standard of Review

[*P13] [HN8] We review a summary judgment decision independently, employing the same methodology as the circuit court. *Acuity v. Bagadia, 2008 WI 62, P12, 310 Wis. 2d 197, 750 N.W.2d 817*. In addition, [HN9] we interpret statutes independently of the circuit court and court of appeals, but benefitting from their analyses. *Richards v. Badger Mut. Ins. Co., 2008 WI 52, P14, 309 Wis. 2d 541, 749 N.W.2d 581*. Finally, [HN10] whether federal preemption applies is a question of federal law that we review independently. *Int'l Ass'n of Machinists & Aerospace Workers v. U.S. Can Co., 150 Wis. 2d 479, 487, 441 N.W.2d 710 (1989)*.

B. Riegel v. Medtronic

[*P14] The United States Supreme Court has given significant direction with respect to the preemptive effect of *21 U.S.C. § 360k(a)* when a defendant in a state law tort claim [**15] has received device-specific premarket approval for a Class III medical device that is alleged to have caused harm. In its 2008 decision in Riegel, which was released subsequent to the court of appeals' decision in this case, the Supreme Court confirmed that [HN11] device-specific premarket approval of a Class III medical device constitutes a federal "requirement" within the meaning of *§ 360k(a)*:

> Premarket approval . . . imposes "requirements" under the [Medical Device Amendments] . . . . Unlike general labeling duties, premarket approval is specific to individual devices. [Premarket approval] is federal safety review. . . . [T]he FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness . . . . [T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

Riegel, 128 S. Ct. at 1007. In resolving this issue, the Court eliminated the split among federal circuits, and adopted the position of the majority of [**16] the federal courts.

[*P15] With respect to whether *21 U.S.C. § 360k(a)* precludes state tort claims that relate "to the safety or effectiveness of" premarket-approved devices because they are "state requirements," Riegel also held that it did. The Supreme Court explained:

> [HN12] Absent other indication, reference to a State's "requirements" includes its common-law duties. . . . [C]ommon-law liability is "premised on the existence of a legal duty," and a tort judgment therefore establishes that the defendant has violated a state-law obligation. . . . And while the common-law remedy is limited to damages, a liability award "'can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'"
>
> [With respect to premarket approval], there is nothing to contradict this normal meaning. To the contrary, in the context of this legislation excluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturer's [devices] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries [**17] under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court. . . . [I]t is implausible that the [Medical Device Amendments] was meant to "grant greater power (to set state standards 'different from, or in addition to' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." That perverse distinction is not required or even suggested by the broad language Congress chose in the [Medical Device Amendments], and we will not turn somersaults to create it.

Riegel, 128 S. Ct. at 1008 (citations omitted).

[*P16] Again, the Court resolved the federal circuit split, adopting the position of the majority of circuits that have considered [**18] the issue. In doing so, the Supreme Court noted that under the Medical Device Amendments, "the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of @50 States to all innovations." *Id. at 1009*.

[*P17] The device at issue in Riegel was one for which supplemental approval had been issued. We shall assume for the sake of our discussion that it was the latest supplemental approval given for that medical device because the Supreme Court did not discuss whether a supplemental approval given at a subsequent date would have had any effect on an earlier approved device sold after a subsequent supplemental approval had issued. In the case before us, the original Marquis 7230 defibrillator is the subject of the Blunts' claims, and the Marquis 7230 that was given supplemental approval is not at issue. With these principles in mind, we now proceed to discuss the Blunts' claims in light of Riegel.

C. Riegel and the Blunts' Claims

[*P18] Riegel holds that [HN13] state tort claims based on injuries caused by a Class III medical device that was granted device-specific [**19] premarket approval may be preempted by *21 U.S.C. § 360k(a)*. Id. State tort claims based on such medical devices are preempted when they relate "to the safety or effectiveness of the device." *Id. at 1007*. In addition, such claims must be "different from, or in addition to," the federal requirement of premarket approval. *Id. at 1011*.

[*P19] The Blunts contend that Medtronic is liable under theories of negligence and strict products liability due to the condition of the original Marquis 7230 defibrillator when it was implanted into Joseph Blunt. Premarket approval is specific to each individual Class III medical device, and it is the federal safety review of each such device. *Id. at 1007*. Accordingly, we must determine whether the Blunts' claims of negligence and strict products liability relate to the safety of the original Marquis 7230 defibrillator. [12] Id. We consider each claim in turn.

12 The Blunts also alleged loss of consortium. That claim is derivative of the negligence and strict liability claims made by Joseph Blunt. *Peters v. Menard, Inc., 224 Wis. 2d 174, 193 n.8, 589 N.W.2d 395 (1999)* ("[L]oss

of consortium claims are derivative."); *Kottka v. PPG Indus., Inc., 130 Wis. 2d 499, 521, 388 N.W.2d 160 (1986)* [**20] ("The claim for a loss of consortium is derivative, in the sense that it does not arise unless the other spouse has sustained a personal injury.") (citing *Fitzgerald v. Meissner & Hicks, Inc., 38 Wis. 2d 571, 581, 157 N.W.2d 595 (1968))*. As a result, the merits of the loss of consortium claim would be considered only if one or both of the first two claims were viable.

[*P20] With respect to negligence, the Blunts' complaint alleged that "Medtronic was negligent in the design, testing, manufacture, marketing, warnings and sale of the [defibrillator] which was implanted in plaintiff," and the "negligence of . . . Medtronic was a proximate cause of the injuries and damages sustained by plaintiffs." These allegations assert that the original Marquis 7230 defibrillator could have been safer to use, despite Medtronic's obtaining device-specific premarket approval from the FDA, had Medtronic not been negligent. As a result, the Blunts' negligence claim does relate to the safety of the original Marquis 7230 defibrillator, as "safety" is used in *21 U.S.C. § 360k(a)* according to Riegel.

[*P21] With respect to strict liability, the Blunts' complaint alleged that: (1) Medtronic's original Marquis 7230 defibrillator, [**21] "as manufactured, designed, tested, marketed and sold by . . . Medtronic[,] was in a defective and unreasonably dangerous condition to users when it left the possession and control of . . . Medtronic"; (2) Medtronic's original Marquis 7230 defibrillator "was defective in that it had a potential battery shorting mechanism which could cause rapid battery depletion thereby rendering the [defibrillator] useless and unavailable to shock or pace the heart into a normal rhythm if plaintiff suffered a rapid, life threatening heart rhythm disturbance"; and (3) "[t]he unreasonably dangerous and defective condition of the [defibrillator] was a proximate cause of the damages sustained by plaintiffs."

[*P22] Here again, the Blunts assert that, despite receiving device-specific premarket approval for the original Marquis 7230 from the FDA, Medtronic designed and sold a Class III medical device that was "defective and unreasonably dangerous." That theory of liability is based on allegations that draw into question the safety of a Class III device for which the FDA granted device-specific premarket approval. Therefore, it is a claim that relates "to the safety or effectiveness of" such a device within the [**22] meaning of *21 U.S.C. § 360k(a)*, as construed in Riegel.

[*P23] We next consider the second step in our Riegel analysis: whether the state law tort claims of negligence and strict products liability are requirements "different from, or in addition to" the federal requirement. We begin by noting that these tort claims are the same tort claims that the Supreme Court held were requirements that were "different from, or in addition to," the federal requirement of premarket approval in *Riegel. Id. at 1007*.

[*P24] As the Supreme Court explained, "[i]n *[Medtronic, Inc. v.] Lohr, [518 U.S. 470, 512, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)]* five Justices concluded that [HN14] common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be preempted by federal requirements specific to a medical device." Id. The Supreme Court concluded, "[w]e adhere to that view." Id. In so doing, the Supreme Court distinguished Lohr, wherein it had concluded that the claims made for use of a pacemaker were not preempted because the pacemaker was subjected to only a "substantial-equivalence review under § 510(k)" by the FDA. [13] Id. This was not the rigorous review of premarket approval. Id. Stated otherwise, the pacemaker at [**23] issue in Lohr had not received FDA device-specific premarket approval. Id.

13 Many medical devices were already on the market when Congress enacted the Medical Device Amendments to the Food, Drug and Cosmetic Act. *Medtronic, Inc. v. Lohr, 518 U.S. 470, 477-78, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)*. Class III devices that were substantially similar to those earlier marketed devices could be marketed without the rigorous premarket review. *Id. at 478-79*. The pacemaker at issue in Lohr was such a device. *Id. at 480*.

[*P25] Here, the FDA granted Medtronic device-specific premarket approval for the original Marquis 7230 defibrillator. Accordingly, the state law claims of negligence and strict liability do impose requirements that are different from or in addition to the federal requirement of premarket approval. Id. Therefore, the only question that was not directly addressed in Riegel is whether the FDA supplemental premarket approval of the Marquis 7230 defibrillator affects the preemption holdings and reasoning of Riegel in regard to the originally approved Marquis 7230 defibrillator.

D. The Supplemental Approval of the Marquis 7230

[*P26] The Blunts argue that their claims are not preempted because when Medtronic obtained supplemental [**24] premarket approval of its Marquis 7230 defibrillator with the design changes addressing the shorting problem, the effect of the FDA's premarket approval of the original defibrillator was "superseded." [14] Stated otherwise, the Blunts

contend that after Medtronic received supplemental premarket approval for the Marquis 7230 and sold its original Marquis 7230, Medtronic sold a device that was no longer subject to a federal "requirement." Under that scenario, the Blunts contend, no federal "requirement" existed to preempt their state tort claims.

> 14 At oral argument, counsel for the Blunts was difficult to pin down on what he meant by saying that the original premarket approval was "superseded" by the supplemental approval. However, he appeared to contend both that the federal requirement evidenced by premarket approval for the original Marquis 7230 defibrillator was changed when the supplemental approval issued and also that there was no longer a federal requirement relating to the sale of the original Marquis 7230. We address both concepts.

[*P27] At oral argument, both parties acknowledged, with some variation, that: (1) the "original" Marquis 7230 was either the 23rd or 29th supplemental premarket-approved [**25] device; (2) there were either five or eight supplemental premarket-approved defibrillator devices between that original Marquis 7230 and the supplemental Marquis 7230 that addressed the potential shorting problem; and (3) since the first approval, there have been approximately 75 supplemental premarket approvals of the Marquis 7230 defibrillator.

[*P28] We begin by noting that [HN15] Congress expressly preempted requirements that were different from or in addition to the federal requirement of device-specific premarket approval for Class III medical devices. *21 U.S.C. § 360k(a)*; *Riegel, 128 S. Ct. at 1010*. As the Supreme Court explained:

> [HN16] The [Medical Device Amendments] provide[] that no State "may establish or continue in effect with respect to a device . . . any requirement " relating to safety or effectiveness that is different from, or in addition to, federal requirements.

Riegel, 128 S. Ct. at 1010 (emphasis in original). Nothing in the Medical Device Amendments advises that a device-specific approval once given is diminished by a supplemental approval for changes in that device without a further act by the FDA.

[*P29] It is beyond dispute that [HN17] the FDA has the power to withdraw premarket approval or [**26] to recall a device to which it has given premarket approval. *21 U.S.C. § 360e(e)(1)*; *21 U.S.C. § 360h(e)*. As the Supreme Court noted:

> [t]he FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.

Riegel, 128 S. Ct. at 1005.

[*P30] [HN18] Under the comprehensive scheme that Congress has enacted, withdrawal of the manufacturer's right to market its premarket-approved devices is accomplished through affirmative acts of the FDA. There is nothing to suggest that premarket approval ceases without FDA action. For example, federal law directs that for the withdrawal or temporary suspension of premarket approval "due notice and opportunity for informal hearing" must be given. *21 U.S.C. § 360e(e)*1. We also note that the FDA has express authority to recall premarket approved Class III medical devices when the FDA finds "there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death." *21 U.S.C. § 360h(e)(1)*.

[*P31] In addition, Medtronic continued to be obligated to comply with the premarket [**27] approval reporting requirements with respect to the original Marquis 7230 defibrillator, subsequent to supplemental premarket approval of the changes to the defibrillator. *Riegel, 128 S. Ct. at 1005* (citing *21 U.S.C. § 360i*; *21 CFR §§ 814.84(b)(2)*, *803.50(a)*). The samples of the FDA premarket approvals in the record of this case relate:

> Postapproval reports. Continued approval of this [premarket approval] is contingent upon the submission of postapproval reports required under *21 CFR [§] 814.84* at intervals of 1 year from the date of approval of the original [premarket approval].

The content of these premarket approvals is consistent with the discussion in *Riegel*, cited immediately above. Accordingly, if the premarket approval of the original Marquis 7230 defibrillator were not ongoing, there would be no need to direct Medtronic to report at least annually on the results of further use and testing of the device. [15]

> 15 See also *21 U.S.C. § 360e(d)(6)* (providing the standards for supplemental approvals, without mentioning any effect that supplemental approvals may have on prior approvals); *21 CFR § 814.39(c)* (same).

[*P32] We have found nothing in the comprehensive federal regulatory scheme that [**28] suggests a change in device-specific premarket approval of a Class III medical device occurs simply because a subsequent device has received supplemental premarket approval, and the Blunts have identified no such provision in the federal law. Accordingly, we conclude that the supplemental premarket approval that Medtronic received did not affect the federal requirement of premarket approval granted to the original Marquis 7230 defibrillator.

[*P33] Furthermore, the United States Supreme Court has interpreted other federal statutory schemes to which preemption arguments have been made in a manner that supports this conclusion. For example, in *Geier v. American Honda Motor, 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000)*, the United States Department of Transportation had required that new automobiles employ at least one of a variety of approved passive restraint systems, including automatic seatbelts and airbags. *Geier, 529 U.S. at 875-76*. Geier sued Honda, alleging liability based on a theory that Honda had a duty to install airbags, even though the federal regulations explicitly permitted other passive restraint systems such as automatic seatbelts. *Id. at 881*. [**29] The Supreme Court, in rejecting Geier's argument, stated:

> In effect, petitioners' tort action depends upon its claim that manufacturers had a duty to install an airbag . . . . Such a state law--i.e., a rule of state tort law imposing such a duty--by its terms would have required manufacturers of all similar cars to install airbags rather than other passive restraint systems, such as automatic belts or passive interiors . . ., even though [the regulation] required only that 10% of a manufacturer's nationwide fleet be equipped with any passive restraint device at all.

Id. Since the state tort claims in Geier would have held automobile manufacturers liable for manufacturing automobiles without airbags and the federal regulations permitted the manufacturers to use other restraints, the state tort claims were preempted due to conflict preemption, a form of implied preemption. [16] Id.

> 16 In *Geier v. American Honda Motor, 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000)*, the Supreme Court considered both the express preemption provisions in the federal law and implied preemption. Due to a savings clause in the express preemption provision, the Court concluded that express preemption did not bar Geier's tort claim. *Id. at 868*. [**30] There is no savings clause in *21 U.S.C. 360k(a)*.

[*P34] Applying the reasoning of *Geier* to this case, we note that Medtronic had received FDA device-specific premarket approval to sell both the original and the supplemental defibrillators. The Blunts acknowledge this, yet the Blunts' tort claims seek to impose liability for selling the original Marquis 7230 defibrillator.

[*P35] While the ultimate holding in Geier was based on implied preemption and our decision is based on express preemption, the facts before us are analogous to the facts in Geier because in Geier the federal government approved airbags and also other restraints, such as lap and shoulder belts. *Id. at 876*. Here, both the original defibrillator and the supplemental defibrillator were approved by the federal government.

[*P36] In Geier, Honda had installed airbags in some of its autos, in conformance with federal regulation; however, Geier was injured in an auto that contained lap and shoulder belts, also in conformance with federal regulations. *Id. at 865*. Here, Medtronics sold both defibrillators and Blunt sought recovery based on the implantation of the original defibrillator, which defibrillator was also in conformance with the federal [**31] regulation.

[*P37] In Geier, the Court upheld a preemption defense for the lap and shoulder belts, concluding that because both types of restraint had been federally approved, a state tort claim would conflict with the federal scheme under which the approvals had been granted. *Id. at 886*. Here, we uphold a preemption defense, albeit based on express preemption, for the federally approved original Marquis 7230 defibrillator. In so doing, we conclude, as did the Supreme Court in Geier, that [HN19] the federal government's approval of the supplemental device did not affect the approval of the original device. Accordingly, a state tort claim will be preempted by the original federal approval. [17]

17 Our conclusion that federal approval of the device under review is critical to our decision is supported by the reasoning in *Sprietsma v. Mercury Marine, 537 U.S. 51, 123 S. Ct. 518, 154 L. Ed. 2d 466 (2002)*. Even though Sprietsma's holding turns on implied preemption, its conclusion that preemption did not occur there confirms how important federal governmental action is in a preemption analysis. *Id. at 65-68*.

[*P38] In addition, other courts seem to take for granted that [HN20] a manufacturer often may have a number of different supplemental premarket-approved [**32] devices on the market at any given time. See, e.g., *U.S. ex rel. Gilligan v. Medtronic, Inc., 403 F.3d 386, 388 (6th Cir. 2005)* (discussing premarket approval and supplemental approval for several pacemakers applied for and obtained at the same time); *Scott v. CIBA Vision Corp., 38 Cal. App. 4th 307, 44 Cal. Rptr. 2d 902 (Cal. Ct. App. 1995)* (preempting claims for an eye injury that occurred when the wrong solution was used with a contact lens after supplemental approval had been given to use a red top on the container for that solution instead of the earlier approved white top that was used on the container of the solution that caused the injury).

[*P39] Finally, [HN21] supplemental approvals do not necessarily occur because newer versions are more safe than predecessor versions, but rather, because the law requires premarket approval for most changes in design. For example, under *21 C.F.R. § 814.39(a)*, supplemental approval must be obtained when the proposed changes allow for a new use of the device, affect the labeling or packaging of the device or require a different facility to process the device. Therefore, we conclude that when a manufacturer obtains supplemental approval for a medical device, absent further FDA [**33] action, prior approvals of the device remain valid and accordingly the federal requirement established by premarket approval is ongoing.

[*P40] The relevant federal statutes, the FDA's regulations and the relevant case law support preemption by the device-specific premarket approval of the original Marquis 7230 defibrillator. Therefore, that premarket approval remained the federal requirement that preempts the Blunts' claims under *21 U.S.C. § 360k(a)*. Accordingly, pursuant to *21 U.S.C. § 360k(a)*, as interpreted in *Riegel,* we conclude that the Blunts' state law tort claims are preempted.

[*P41] In an effort to get around the holdings in Riegel, the Blunts also contend that the federal statute's use of the word "requirement" means that the medical device manufacturer is "required" to sell only one version of the device. The Blunts explain that since Medtronic had the option of selling either the original Marquis 7230 defibrillator or the supplemental Marquis 7230, it was no longer "required" to sell only the original defibrillator. Therefore, they contend that their claims that arise from the use of the original Marquis 7230 are not preempted. Stated otherwise, they argue that since there is no longer [**34] a federal "requirement" that relates solely to the original Marquis 7230, state tort law requirements have no federal requirement from which they are "different from, or in addition to." Judge Fine also employed this reasoning in his dissent. *Blunt, 2007 WI App 191, 305 Wis. 2d 354, P22, 738 N.W.2d 143* (Fine, J., dissenting) ("The Majority asks and answers the wrong question. [T]he nub here is: Whether Medtronic is protected by the preemption doctrine when it had the option under federal law of selling two approved devices.") (emphasis in original). We reject this argument.

[*P42] Riegel provides a precise meaning for the term, "requirement," as used in *21 U.S.C. § 360k(a)*. It is not the meaning suggested by the Blunts. [HN22] Through the federal requirement of device-specific premarket approval, "the FDA requires a device to be made with almost no deviations from the specifications in its approval application." *Riegel, 128 S. Ct. at 1007*. That is, "requirement" under *§ 360k(a)* refers to safety and efficacy federal requirements that a manufacturer must satisfy before its product may be approved and marketed. State tort claims based on the safety of a device also are "requirements"; however, they are state requirements, rather [**35] than federal requirements. For example under Wisconsin law, a manufacturer is required to design its device to prevent it from being unreasonably dangerous. See, e.g., *Dippel v. Sciano, 37 Wis. 2d 443, 459, 155 N.W.2d 55 (1967)*.

[*P43] As a result, [HN23] the term, "requirement," as it is construed in Riegel, encompasses both federally mandated criteria [18] for medical devices before they can be marketed and sold (a federal requirement) and state tort claims that require manufacturers to design their devices with a certain level of safety (a state requirement) before they are marketed and sold in order to avoid tort liability. However, under *Riegel*, the term, "requirement," does not mean that a manufacturer is "required" to sell one particular approved device among several devices that have been given device-specific premarket approval. To the contrary, premarket approval does not require the manufacturer to sell any premarket approved medical devices at all. Accordingly, the Blunts' arguments do not change our conclusion stated above that pursuant to *21 U.S.C. § 360k(a)*, as interpreted in Riegel, the Blunts' state law tort claims are preempted.

18 Not all approvals received under the Medical Device Amendments [**36] constitute federal "requirements" under *21 U.S.C. § 360k(a)*, as interpreted in Riegel. For example, devices that receive FDA approval because

they are "substantially equivalent" to premarket approval-exempted devices under *21 U.S.C. § 360c(f)(1)(A)* are not subject to the federal requirement, and tort claims based on such devices are not preempted. See *Riegel, 128 S. Ct. at 1007*; *Lohr, 518 U.S. at 493-94*.

III. CONCLUSION

[*P44] Our decision in this case turns on whether the Blunts' state law tort claims are preempted by federal law. In order to decide this issue, we must answer three questions. The first is whether Medtronic's Marquis 7230 implantable cardioverter defibrillator (the Marquis 7230 defibrillator), which was approved under the Food and Drug Administration's (FDA) premarket approval process, *21 U.S.C. § 360e*, met the federal "requirement" specific to that device, pursuant to *21 U.S.C. § 360k(a)*, when it received premarket approval. The second question is whether the Blunts' common law claims, which allege negligence, strict liability and loss of consortium, constitute state requirements that are "different from, or in addition to," the federal requirement. The third question is [**37] whether the preemption analysis of Riegel applies to claims against the Marquis 7230 defibrillator, even though supplemental premarket approval was given to a later defibrillator. Because we conclude that the United States Supreme Court's decision in Riegel provides definitive direction on these questions, we answer all of them in the affirmative. We therefore conclude that *§ 360k(a)* preempts the Blunts' claims. Accordingly, we affirm the decision of the court of appeals. *By the Court*.--The decision of the court of appeals is affirmed.

CONCUR BY: ANN WALSH BRADLEY

CONCUR

[*P45] ANN WALSH BRADLEY, J. *(concurring in the judgment)*. I write separately in order to express my concern that the United States Supreme Court's interpretation of the 1976 Medical Device Amendments does not adequately protect the safety of the citizens of Wisconsin. See *Riegel v. Medtronic, Inc., U.S. , 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008)*. With one stroke of a pen, it has diminished the states' traditional authority over the development of the common law and substituted instead mandatory adherence to a regulatory standard that may be substandard. I do not believe that such adherence was mandated by the express language of the amendments, although [**38] I acknowledge that I am bound by the Supreme Court's interpretation.

[*P46] I also write separately because I disagree with the majority's reliance on *Geier v. American Honda Motor Co., Inc., 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000)*. The Geier case turns on implied preemption. Nevertheless, the majority uses Geier to conclude that the Blunt's tort claims must be dismissed based on express preemption. [19] Because express preemption and implied preemption are distinct legal theories based on different facts and analysis, Geier does not support the majority's determination in this case.

19 The majority misconstrues the Blunts' arguments. The Blunts argue that their tort claims are not state requirements "different from, or in addition to" federal requirements because Medtronic had the option of selling one of two approved devices. Thus, the Blunts assert that Medtronic was allowed to--but was not required to--sell the allegedly defective device that was implanted in Joseph Blunt.

The majority addresses the Blunts' argument only as an afterthought. See majority op., PP41-43. Instead, the majority focuses on an argument never advanced by the Blunts, that is, whether supplemental approval of a subsequent device extinguished [**39] the prior device's Food and Drug Administration (FDA) approval. See majority op., PP26-40. This is an argument that does not appear in the Blunts' brief, and that counsel for the Blunts specifically disclaimed during oral argument. See Wisconsin Court System, Supreme Court Oral Arguments, http://wicourts.gov/opinions/soralarguments.htm (search "Party name" for "Blunt"; then follow "Playback" link) at 19:15.

I

[*P47] The purpose of the federal Medical Devices Amendments of 1976, *21 U.S.C. § 360 et seq.*, was "to provide for the safety and effectiveness of medical devices intended for human use[.]" 90 Stat. 539 (1976) (preamble); see also *Medtronic, Inc. v. Lohr, 518 U.S. 470, 474, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)*. In response to public health disasters involving unsafe medical devices such as the infamous Dalkon Shield, Congress determined that these devices should be more stringently regulated than most products. *Riegel, U.S. at , 128 S. Ct. at 1003*.

[*P48] It is the responsibility of the state legislature and courts to develop a tort system that protects the health and safety of the citizens they serve. The United States Supreme Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of [**40] action." *Lohr, 518 U.S. at 485*. "[A]s a rule," the United States Supreme Court "should be and [is] reluctant to federalize matters traditionally covered by state common law." *Patterson v. McLean Credit Union, 491 U.S. 164, 183, 109 S. Ct. 2363, 105 L. Ed. 2d 132 (1989)* (superseded by statute) (quotations omitted). Instead, the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Lohr, 518 U.S. at 485* (quotations omitted).

[*P49] The Medical Device Amendments provide that no State may "establish or continue in effect . . . any requirement" that is "different from, or in addition to" the federal requirements and "which relates to the safety or effectiveness of the device[.]" *21 U.S.C. § 360k(a)*. In 1996, the Court stated that "it would take language much plainer than the text of *§ 360k(a)* to convince us that Congress intended that result [that state tort claims are preempted]." *Lohr, 518 U.S. at 487*.

[*P50] However, 12 years later, with precisely the same language in force, the Court concluded that the language was apparently plain enough. The Court determined that state tort law claims are state "requirements" [**41] and that the express language of *§ 360k(a)* preempts them. *Riegel, U.S. at , 128 S. Ct. at 1008*.

[*P51] Despite basing its conclusion on a determination that the language is plain, the Court turned to the policy reasons supporting its determination. The policy reason cited by the Supreme Court in favor of preemption is that it is better for one centralized agency--the Food and Drug Administration (FDA)--to do the necessary cost-benefit analysis in determining whether a device is safe enough for the market:

> It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available--the text of the statute--suggests that the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations. [20]

Riegel, U.S. at , 128 S. Ct. at 1009. [21]

20 Concurring in the judgment, Justice Stevens stated:

> There is nothing in the preenactment history of the [Medical Device Amendments] suggesting that Congress thought state tort remedies had impeded the development of medical devices. [**42] Nor is there any evidence at all to suggest that Congress decided that the cost of injuries from Food and Drug Administration-approved medical devices was outweighed "by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." That is a policy argument advanced by the Court, not by Congress.

Riegel v. Medtronic, Inc., U.S. , 128 S. Ct. 999, 1012, 169 L. Ed. 2d 892 (2008) (Stevens, J., concurring in part and concurring in the judgment) (citations omitted).

21 A recent law review article closely tracks this rationale, declaring that "preemption is necessary to ensure that federal regulatory agencies, like the Food and Drug Administration (FDA), are the only governmental actors able to impose requirements on manufacturers--thereby ensuring a nationally standardized system of safety regulations without myriad local variations." Note, Preemption of State Common Law Claims, *122 Harv. L. Rev. 405, 405 (2008)*.

[*P52] This is a policy rationale that may be meritorious if the premarket approval process provided at least minimum assurances of safety. It presumes that the FDA premarket approval process is indeed rigorous and that [**43] the devices approved are safe for use. Recent reporting on the FDA calls these presumptions into question.

[*P53] Recently, there has been a flood of criticism directed at the FDA approval process, much of the criticism coming from whistleblowers within the FDA itself. It is not at all apparent that the FDA approval process actually guarantees a minimum level of safety for medical devices. A January 2009 letter from nine FDA scientists could not be

more clear: "The purpose of this letter is to inform you that the scientific review process for medical devices at FDA has been corrupted and distorted by current FDA managers, thereby placing the American people at risk." Letter from nine FDA scientists (names redacted), to John D. Podesta, Presidential Transition Team 1 (Jan. 7, 2009).

[*P54] The letter charges managers of the Center for Devices and Radiological Health (CDRH) with "corrupting and distorting the scientific evaluation of medical devices, and . . . interfering with our responsibility to ensure the safety and effectiveness of medical devices before they are used on the American public." Id. The scientists further explained:

> Managers at CDRH have ignored the law and ordered physicians and [**44] scientists to assess medical devices employing unsound evaluation methods, and to accept non-scientific, nor clinically validated, safety and effectiveness evidence and conclusions, as the basis of device clearance and approval. Managers . . . have ignored serious safety and effectiveness concerns of FDA experts. Managers have ordered, intimidated, and coerced FDA experts to modify scientific evaluations, conclusions and recommendations in violation of the laws, rules and regulations and to accept clinical and technical data that is not scientifically valid nor obtained in accordance with legal requirements . . . . These same managers have knowingly tried to avoid transparency and accountability by failing to properly document the basis of their non-scientific decisions in administrative records.

Id. at 2. The letter concludes that the current FDA approval process is "a clear and silent danger to the American public." Id. at 3.

[*P55] As one example of the FDA's ineffectiveness in ensuring basic device safety, the FDA scientists point to the 1998 approval of a mammography computer-aided detection device. Id. The scientists charge that the FDA approved the device even though there was no clinical [**45] evidence of improved cancer detection. Id. Further, the FDA carried out no post-marketing reassessment of approved devices and "ignor[ed] accumulating clinical evidence provided by independent research publications revealing that these devices were ineffective and potentially harmful when used in clinical practice." Id.

[*P56] Congress is aware of some of the problems within the FDA, and the House Committee on Energy and Commerce conducted an investigation on the matter in October of 2008. As a result of its findings, the Committee sent a letter to the Commissioner of the FDA, stating that the Committee "recently received compelling evidence of serious wrongdoing in connection with FDA's review, clearance, and approval process of medical devices." [22] The letter states that FDA scientists "supplied substantial evidence demonstrating that medical devices submitted for FDA review . . . have been received and/or cleared or approved in violation of agency regulation and guidance mandated to assure safety and effectiveness." [23]

22 Letter from Representative John D. Dingell and Representative Bart Stupak, Chairmen, U.S. House of Representatives Committee on Energy and Commerce, to the Honorable Andrew [**46] C. von Eschenbach, Commissioner, U.S. Food and Drug Administration 1 (Nov. 17, 2008).

23 Id.

[*P57] The preemption doctrine should not be employed to allow for the normal standard of care to be substandard care. I conclude, as I must, that Riegel controls and that the Blunts' tort claims are preempted. [24] However, the result may be no meaningful protection for Wisconsin patients.

24 Tort law claims are not preempted, however, to the extent that they seek damages for a manufacturer's violation of federal requirements:

> Where a state cause of action seeks to enforce [a federal] requirement, that claim does not impose a requirement that is "different from, or in addition to," requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. *Section 360k* does not preclude States from imposing different or additional remedies, but only different or additional requirements.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 513, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (O'Connor, J., concurring in part and dissenting in part) (emphasis in original); see also *Riegel, 128 S. Ct. at 1011* ("*§ 360k* does not prevent [**47] a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.").

II

[*P58] I also write separately to express my disagreement with the majority's discussion of *Geier v. American Honda Motor Co., Inc., 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000)*. See majority op., PP33-37. The basis for the majority's conclusion in this case (and for the Supreme Court's conclusion in Riegel) is express preemption. Yet, Geier is a case that turns on conflict preemption, a form of implied preemption. [25] Because the cases turn on distinct legal theories, I do not find Geier relevant to the court's determination in this case.

25 In fact, in Geier the Court determined that a Department of Transportation safety standard did not expressly preempt state tort law claims. *Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 868, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000)*. However, based on the Department's comments which accompanied the standards and the drafting history, the Court determined that the claim was nonetheless preempted under the doctrine of implied preemption. *Id. at 874*.

[*P59] Express preemption and implied preemption are separate legal theories, based on [**48] distinct factual inquiries. Express preemption is exactly what it sounds like--the text of a congressional enactment explicitly provides that state law claims are preempted. See *English v. Gen. Elec. Co., 496 U.S. 72, 79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990)*. Implied preemption, however, comes in several stripes and involves a more nuanced analysis.

[*P60] One form of implied preemption is "conflict preemption." Under this doctrine, a particular state law is preempted because of an "actual conflict" with a federal regulation--even in the absence of a broad congressional mandate to preempt all state law in the area. See id. State law is preempted due to a conflict with federal law when it is impossible for a party to simultaneously comply with state and federal requirements, or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Id.

[*P61] The majority appears to suggest that a case about implied preemption lends support to the majority's express preemption analysis. That is, the Blunts' claims are expressly preempted because the facts of the case are "analogous" to the facts in a case regarding a different Congressional act and in which a different preemption [**49] doctrine applies. Majority op., P35. This cannot be. Because the majority here takes a superficial approach to the facts and the law in Geier, it misses the essence of that case and misapplies its holding.

[*P62] In Geier, the Supreme Court determined that the plaintiff's state tort law claim was impliedly preempted via the doctrine of conflict preemption. *529 U.S. at 874*. Geier had filed a tort action against Honda, alleging negligence for failure to install an airbag in her car. *Id. at 865*. The Court examined the Federal Motor Vehicle Safety Standards, promulgated by the Department of Transportation, to determine whether they preempted Geier's claim. The safety standards required automobile manufacturers to equip some--but not all--of their vehicles with airbags. Id.

[*P63] In determining that Geier's claim was impliedly preempted, the Court looked to the comments and drafting history of the safety standards to determine the Department's intent. *Id. at 874-79*. In creating the safety standards, the Department had "rejected a proposed . . . 'all airbag' standard because of safety concerns (perceived or real) associated with airbags[.]" *Id. at 879*. Instead, the Department determined that "a mix of [**50] devices would help develop data on comparative effectiveness [and] would allow the industry time to overcome the safety problems and the high production costs associated with airbags[.]" Id. The safety standards reflected the Department's "policy judgment that safety would best be promoted if manufacturers installed alternative protection systems in their fleets rather than one particular system in every car." *Id. at 881* (emphasis in original).

[*P64] In Geier, the Court concluded the Department made an affirmative determination that it did not want manufacturers to install airbags in all of their automobiles. Because Geier's tort claim would require manufacturers to install airbags in all of their automobiles or risk liability, the state tort claim actually conflicted with the accomplishment of a federal objective. Therefore, it was impliedly preempted. See id.

[*P65] In this case, the facts in the record do not support a finding of implied preemption. At the time that Blunt received the allegedly defective defibrillator, the FDA permitted Medtronic to market both the original and the improved defibrillator. Majority op., P32. There is no indication in the record, however, that the FDA made an [**51]

affirmative decision that its policy objectives would be best served if Medtronic sold both types of defibrillators at once. Without such affirmative determination, state tort law claims do not frustrate the accomplishment of the FDA's objective and are not preempted under the doctrine of conflict preemption.

[*P66] For the above reason, I determine that the reasoning of Geier is inapt in this case. Because I do not agree with the majority's blending of preemption doctrines, I respectfully concur.

[*P67] I am authorized to state that SHIRLEY S. ABRAHAMSON, C.J. joins this concurrence.