crowell moring

CLIENT ALERT

U.S. Supreme Court Limits Lawsuits Against Medical Device Manufacturers – Products Approved Under FDA's PMA Process Exempt From State Tort Law Claims

Feb.21.2008

Yesterday the U.S. Supreme Court decided that federal medical device law prohibits state tort claims against manufacturers whose products pass the Food and Drug Administration's ("FDA's") pre-market approval ("PMA") process.

In Riegel v. Medtronic Inc., in an 8-1 decision, the U.S. Supreme Court barred a suit claiming a New York man suffered permanent injury when a Medtronic heart catheter burst during an angioplasty procedure. The Supreme Court ruled that federal medical device law preempts state tort claims against manufacturers whose products are approved through the FDA's PMA process. Under the Food Drug and Cosmetic Act, federal law bars the imposition of any state "requirements" that are "different from" or "in addition to" requirements established by the FDA. The Supreme Court previously held that this express preemption provision does not bar state law claims against makers of devices that have gone through FDA's 510(k) process, also known as "pre-market notification," because that process does not create device-specific federal requirements that trigger preemption. In Medtronic Inc. v. Lohr, 518 U.S. 470 (1996) the Supreme Court left unanswered the question of whether the PMA process—which is more rigorous than the 510(k)—creates the kind of device-specific federal requirements that are needed to trigger preemption.

In the Riegel case, petitioner Donna Riegel argued that claims arising out of injuries caused by the bursting of a balloon catheter during angioplasty should be allowed to go forward, even though the catheter used in surgery received PMA approval. The Supreme Court, however, rejected that argument and held that the express preemption language governing medical devices barred such litigation.

The decision aligns with the majority of cases in which courts have considered the issue of "whether approval via the PMA process" bars state claims. The decision will impact thousands of lawsuits, including cases in which implantable devices are at issue. The decision also may have implications for drug manufacturers.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.