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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA, Plaintiff, v. GENERAL ELECTRIC COMPANY dba GE HEALTHCARE and GE OEC MEDICAL SYSTEMS, INC., corporations, and JOSEPH M. HOGAN, and PETER MCCABE, individuals, Defendants.	Civ. No. COMPLAINT FOR PERMANENT INJUNCTION **Judge Tena Campbell** **DECK TYPE: Civil** **DATE STAMP: 01/12/2007 @ 14:56:18** **CASE NUMBER: 2:07CV00017 TC**

Plaintiff, United States of America, by Brett L. Tolman, United States Attorney for the District of Utah, respectfully represents to this Court as follows:

1. This proceeding is brought under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 332(a), to enjoin defendants General Electric Company dba GE Healthcare and GE OEC Medical Systems, Inc., corporations, and Joseph M. Hogan, Senior Vice President, General Electric Company, and President and Chief Executive Officer, GE Healthcare, and Peter McCabe, President and Chief Executive Officer, GE Healthcare Surgery and President and Chief Executive Officer, GE OEC Medical Systems, Inc. (collectively, "Defendants"), from violating:

a. 21 U.S.C. § 331(a) by causing the introduction into interstate commerce of articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. § 351(h), and misbranded within the meaning of 21 U.S.C. § 352(t)(2); and

b. 21 U.S.C. § 331(k) by causing articles of device to become adulterated within the meaning of 21 U.S.C. § 351(h), and misbranded within the meaning of 21 U.S.C. § 352(t)(2), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337 and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

4. Defendant GE OEC Medical Systems, Inc. (GE OEC) is incorporated under the laws of Delaware and is doing business at 384 and 640 Wright Brothers Drive, Salt Lake City, Utah, and at 439 S. Union Street, Lawrence, Massachusetts. GE OEC is engaged in the design, manufacture, and distribution in interstate commerce of various articles of device.

5. Defendant General Electric Company dba GE Healthcare (GE Healthcare) is the parent corporation of GE OEC. General Electric Company's corporate headquarters are located at 3135 Easton Turnpike, Fairfield, Connecticut. The corporate headquarters of the GE Healthcare division of General Electric Company are located at Pollards Wood Nightingales Lane, Chalfont St. Giles, Great Britain.

6. Defendant Joseph M. Hogan, an individual, is Senior Vice President, General Electric Company and President and Chief Executive Officer of the GE Healthcare division of General Electric Company. Mr. Hogan maintains his office at the corporate headquarters of the

GE Healthcare division of General Electric Company in Great Britain. GE OEC reports directly to Mr. Hogan, and he is responsible for the operations of the GE OEC facilities in Salt Lake City, Utah, and Lawrence, Massachusetts.

7. Defendant Peter E. McCabe is the President and Chief Executive Officer of GE Healthcare Surgery. He is also President and Chief Executive Officer of GE OEC Medical Systems, Inc. He performs his duties at 384 Wright Brothers Drive, Salt Lake City, Utah, within the jurisdiction of this Court. Mr. McCabe has previously served as the Chief Quality Officer of GE Healthcare. Mr. McCabe is responsible for the operations of the GE OEC facilities in Salt Lake City, Utah, and Lawrence, Massachusetts.

8. Defendants have been, and are now, engaged at the GE OEC facilities in Salt Lake City, Utah, in receiving, designing, manufacturing, processing, packing, labeling, storing, and distributing in interstate commerce various articles of device. Defendants' products include, but are not limited to, a variety of radiological image processing systems and image-intensified fluoroscopic x-ray systems, including, but not limited to: 9900 Elite C-Arm System, 9900 Elite NAV C-Arm System, 9800 C-Arm System, 2800 UroView System, 6800 MiniView System, Insta-Trak 3500 NAV System, and ENTrak 2500 NAV System (hereafter, surgical imaging systems). Defendants have been, and are now, engaged at the GE OEC facility in Lawrence, Massachusetts, in designing devices manufactured at the GE OEC facilities in Salt Lake City, including the navigation and visualization (NAV) products that are devices and components of certain surgical imaging systems.

9. Defendants' surgical imaging systems are labeled for and intended to provide fluoroscopic images of patients during diagnostic, surgical, and interventional procedures. The

surgical imaging systems are devices within the meaning of the FDCA, 21 U.S.C. § 321(h), in that they are instruments, apparatuses, implements, or machines that are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, or treatment of disease in man or other animals.

10. To ensure that devices will be safe and effective, and otherwise in compliance with the FDCA, Congress authorized the Secretary of the Department of Health and Human Services (Secretary) to prescribe regulations requiring that devices be manufactured in conformity with current good manufacturing practice (CGMP). 21 U.S.C. § 360j(f)(1). The CGMP requirements are set forth in the Quality System Regulation at 21 C.F.R. Part 820.

11. Congress authorized the Secretary to prescribe regulations requiring device manufacturers and importers to promptly report to the Secretary "any correction or removal of a device undertaken by such manufacturer or importer if the removal or correction was undertaken – (A) to reduce a risk to health posed by the device, or (B) to remedy a violation of [the FDCA] caused by the device which may present a risk to health." 21 U.S.C. § 360i(f)(1). The regulations governing Reports of Corrections and Removals are set forth at 21 C.F.R. Part 806. Congress further authorized the Secretary to prescribe regulations requiring device manufacturers and importers to report to the Secretary "whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices – (A) may have caused or contributed to a death or serious injury, or (B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to

recur." 21 U.S.C. § 360i(a). The Medical Device Reporting regulations are set forth at 21 C.F.R. Part 803. A device is deemed to be misbranded if "there was a failure or refusal . . . (2) to furnish any material or information required by or under [21 U.S.C. § 360i] respecting the device . . . ." 21 U.S.C. § 352(t)(2).

12. The Food and Drug Administration (FDA) inspected Defendants' operations at the GE OEC facilities in Salt Lake City, Utah, between November 15 and December 1, 2004, and between July 31 and August 29, 2006. During these inspections, FDA investigators observed violations of the CGMP regulations as well as the Medical Device Reporting, and Reports of Corrections and Removals regulations. Some of the same violations were observed during both the 2004 and 2006 inspections. FDA inspected Defendants' operations at the GE OEC facility in Lawrence, Massachusetts, between November 6 and December 6, 2006, and December 21 and 28, 2006. During those inspections, FDA investigators observed violations of the CGMP regulations. Defendants were issued written notice of the violations observed by FDA investigators at the conclusion of each of these inspections.

13. Defendants design, manufacture, pack, and store devices that are adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, and the facilities or controls used for, their design, manufacture, processing, packing, and storage do not conform to or are not operated in conformity with CGMP, as described in 21 U.S.C. §360j(f)(1) and the Quality System (QS) regulation for devices found at Title 21, Code of Federal Regulations (CFR), Part 820.

14. Defendants' most recent CGMP violations at the GE OEC facilities in Salt Lake City, Utah, include, but are not limited to, the following:

a. Failure to establish and maintain adequate procedures for validating the device design, as required by 21 C.F.R. § 820.30(g);

b. Failure to establish and maintain adequate procedures for implementing corrective and preventive action (CAPA), as required by 21 C.F.R. § 820.100(a);

c. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, and for ensuring that all complaints are handled in a uniform and timely manner, as required by 21 C.F.R. § 820.198(a); and

d. Failure to validate computer software used as part of the production or the quality system for its intended use according to an established protocol, and to document validation activities and their results, as required by 21 C.F.R. § 820.70(i).

15. Defendants' most recent CGMP violations at the GE OEC facility in Lawrence, Massachusetts, include, but are not limited to, the following:

a. Failure to establish and maintain adequate procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 C.F.R. § 820.30; and

b. Failure to validate computer software used as part of the production or the quality system, for its intended use according to an established protocol, to validate any changes before approval and issuance, and to document validation activities and their results, as required by 21 C.F.R. § 820.70(i).

16. Defendants have misbranded devices within the meaning of the Act, 21 U.S.C. § 352(t)(2), by failing to furnish material or information required by or under 21 U.S.C. § 360i.

Defendants' most recent violations of 21 U.S.C. 352(t)(2) at the GE OEC facilities in Salt Lake City, Utah, include, but are not limited to, the following:

a. Failure to submit a Medical Device Report (MDR) within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a serious injury if the malfunction were to recur, as required by 21 C.F.R. § 803.50(a)(2);

b. Failure to conduct an investigation of each event and evaluating the cause of the event, as required by 21 C.F.R. § 803.50(b)(3); and

c. Failure to submit written reports to FDA of corrections or removals of a device initiated by such manufacturer or importer, as required by 21 C.F.R. § 806.10.

17. Defendants have violated 21 U.S.C. § 331(k) by causing the adulteration of articles of device, as set forth in paragraphs 12-15 of this Complaint, and causing the misbranding of articles of device, as set forth in paragraph 16 of this Complaint while such articles are held for sale after shipment in interstate commerce or after shipment of one or more of their components in interstate commerce. In addition, Defendants have violated 21 U.S.C. § 331(a) by introducing and delivering for introduction into interstate commerce articles of device that are adulterated and misbranded, as set forth above.

18. Defendants are well aware that their practices violate the FDCA and applicable regulations set forth at 21 C.F.R. Parts 803, 806, and 820. FDA issued a written Warning Letter to General Electric Company on March 31, 2005. The letter described the violations observed during the November 15 – December 1, 2004, inspection of the GE OEC facilities in Salt Lake City, Utah.

19. In response to the March 2005 Warning Letter, Defendants promised corrective action. Representatives from GE OEC and GE Healthcare also met with staff from FDA's Denver District Office and from the Center for Devices and Radiological Health (CDRH). In those meetings, representatives from GE OEC and GE Healthcare reiterated their promises to take corrective action.

20. FDA's inspections in August/September 2006 and November/December 2006 at the GE OEC facilities in Salt Lake City, Utah, and Lawrence, Massachusetts, respectively, documented that although Defendants have taken steps to correct the previously observed violations, significant violations continue to exist.

21. Plaintiff is informed and believes that, unless and until restrained by this Court, Defendants will continue to violate 21 U.S.C. § 331(a) and (k) in the manner set forth above.

WHEREFORE, PLAINTIFF PRAYS:

I. That Defendants, General Electric Company dba GE Healthcare and GE OEC Medical Systems, Inc., corporations, and Joseph M. Hogan and Peter E. McCabe, individuals, and each and all of their directors, officers, agents, representatives, employees, successors, assigns, servants, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), be permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any and all of the following acts at or from their Salt Lake City, Utah, or Lawrence, Massachusetts facilities:

A. Introducing, or causing the introduction, into interstate commerce any article of device, as defined in 21 U.S.C. § 321(h); and

B. Manufacturing, processing, packing, labeling, or doing any other act with respect to any article of device, while the article is held for sale after shipment of one or more of its components in interstate commerce,

UNLESS AND UNTIL: Defendants satisfy FDA that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and installation of their surgical imaging systems are in compliance with 21 U.S.C. § 351(h) and the Quality Systems regulation set forth in 21 C.F.R. Part 820; and the requirements of 21 U.S.C. § 352(t)(2) and the regulations set forth at 21 C.F.R. Parts 803 and 806.

II. Authorize FDA, pursuant to this injunction, to inspect Defendants' places of business to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be born by Defendants at the rates prevailing at the time the inspections are performed; and

III. Award the Plaintiff its costs herein and such other and further relief as the Court may deem just and proper.

DATED this 12th day of January, 2007.

Respectfully submitted,

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