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GE OEC Medical Systems Signs Consent Decree with FDA; Agrees to Correct Manufacturing Deficiencies

The U.S. Food and Drug Administration (FDA) today announced that GE OEC Medical Systems, Inc., its parent company, the General Electric Company doing business as GE Healthcare, and two of their top executives have signed a consent decree of permanent injunction related to X-ray surgical imaging systems manufactured by GE OEC Medical Systems. The consent decree prohibits the manufacturing and distribution of specified GE OEC Medical Systems X-ray surgical imaging systems at facilities in Salt Lake City, Utah, and Lawrence, Massachusetts, until the devices and facilities have been shown to be in compliance with FDA's current good manufacturing practice (CGMP) requirements as set forth in the Quality System (QS) regulation for devices.

The decree was filed today in the U.S. District Court for the District of Utah and is subject to court approval.

The X-ray surgical imaging systems subject to the decree are manufactured and designed at GE OEC Medical Systems' facilities in Salt Lake City, Utah, and Lawrence, Massachusetts, and include the 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, as well as their components and accessories. These are radiological image processing and image-intensified fluoroscopic X-ray systems that are used during diagnostic, surgical, and interventional procedures, such as orthopedic, cardiac, critical-care, emergency room procedures, and other imaging applications.

“These devices are used on thousands of patients, and their dependability and accuracy are critical for the successful outcomes of important medical procedures,” said Daniel Schultz, M.D., director of FDA’s Center for Devices and Radiological Health. “When FDA's August 2006 inspection found ongoing CGMP deficiencies at the Utah facility, GE voluntarily stopped distributing devices from that facility and is working with FDA to ensure that necessary corrective actions are fully implemented."

FDA's most recent inspection of the Utah facility, conducted between July 31 and August 29, 2006, revealed CGMP deficiencies, including failure to establish and maintain adequate procedures for validating the device design and failure to establish and maintain adequate procedures for implementing corrective and preventive actions. FDA previously inspected the Utah facility between November 15 and December 1, 2004. Following that inspection, FDA issued a Warning Letter on March 31, 2005, citing violations of the CGMP requirements. The government brought this enforcement action when FDA's 2006 inspections showed inadequate responses to FDA’s requests for corrections in the 2005 Warning Letter.

Under the terms of the consent decree, signed by Joseph M. Hogan, Senior Vice President, GE Company and President and Chief Executive Officer, GE Healthcare, and Peter McCabe, President and Chief Executive Officer of GE OEC Medical Systems and GE Healthcare Surgery, the companies have agreed to take necessary measures to ensure that the X-ray surgical imaging systems manufactured and designed at the Utah and Massachusetts facilities comply with CGMP requirements, as well as FDA regulations for reporting adverse events and malfunctions and device corrections and removals.

The decree also requires that the companies hire an independent expert to conduct inspections of GE OEC Medical Systems facilities in Utah and Massachusetts and certify to FDA that corrections have been made. Manufacturing and distribution can resume at the Utah and Massachusetts facilities once FDA is satisfied that those facilities are in compliance with the law. An outside expert also will conduct yearly audit inspections for four years to assure that the facilities remain in compliance and will submit his/her findings to FDA. FDA may order the companies to stop manufacturing and distributing the X-ray imaging systems if they fail to comply with any provision of the consent decree, the Federal Food, Drug, and Cosmetic Act or FDA regulations.

Under the consent decree, the companies are also required to submit to FDA a corrective action plan for bringing into compliance with the Act the 9900 Elite C-Arm Systems, the 9900 Elite NAV C-Arm Systems, and the 9800 C-Arm Systems that are currently in use in the U.S. by physicians, hospitals, and other facilities. GE OEC Medical Systems also has voluntarily initiated product recalls on several models of its X-ray surgical imaging systems. Copies of the recall notices are available on the company's website at http://www.gehealthcare.com/usen/xr/surgery/oec_info.html.

The consent decree allows the companies to continue to provide routine service maintenance, replacement parts, and accessories for the GE OEC X-ray surgical imaging systems that are already employed in U.S. hospitals and other health care facilities.

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