U.S. Food and Drug Administration
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FDA News Release

Federal judge approves consent decree with Maquet Holding B.V. & Co.

Manufacturing violations cited at three of its medical device companies

For Immediate Release

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Release

A federal judge from the U.S. District Court for the District of New Hampshire has entered a consent decree of permanent injunction against Maquet Holding B.V. & Co. KG (Maquet), and two of the company's officers, Heinz Jacqui and Gail Christie, for repeatedly failing to correct violations at three of its companies, which are also named on the consent decree: Atrium Medical Corporation (Atrium) in Hudson, New Hampshire; Maquet Cardiovascular, LLC (Maquet CV) in Wayne, New Jersey; and Maquet Cardiopulmonary AG (Maquet CP) in Rastatt and Hechingen, Germany.

Maquet and its related companies manufacture a wide variety of medical devices that are commonly used in hospital and health care settings, including oxygenators, tubing sets, catheters, life support systems, and surgical mesh.

Between 2009 and 2013, FDA investigators conducted ten inspections across the three Maquet facilities, and uncovered major violations of the Quality System (QS) regulation, Medical Device Reporting (MDR) regulation, and Correction and Removal (CR) regulation.

During that timeframe, the agency issued two warning letters to the three companies. Additionally, between 2009 and 2014, the FDA is aware of 45 recalls of Maquet-manufactured devices, five of which were classified as Class 1 – representing the most significant risk to patients. The FDA and Maquet entered into the decree to implement immediate controls, with the goal of bringing all facilities into compliance with the Federal Food, Drug & Cosmetic (FD&C) Act and its implementing regulations, including the QS, MDR, and CR regulations.

“Patients must be assured that medical devices are safe, effective, and high quality,” said Jan Welch, acting director of the Office of Compliance in the FDA’s Center for Devices and Radiological Health. “The FDA will remain vigilant in bringing companies that do not meet our regulatory requirements back to a sustainable state of compliance.”

Under the terms of the consent decree, Maquet will stop manufacturing and distributing devices from Atrium’s Hudson facility until the company makes appropriate corrections to ensure compliance with the FD&C Act. Atrium may continue to distribute certain products inside and outside of the United States that are deemed medically necessary under the decree, provided that the U.S. authorized representatives and international customers have signed a Certificate of Medical Necessity (CMN). The following Atrium products will be unavailable under the terms of the decree: ProLite Hernia Mesh; ProLoop Hernia Mesh; C-QUR Hernia Mesh (including Vpatch, Tacshield, FX, Mosaic and Film); Flixene Vascular Graft; and Ivena Vascular Patch.

Maquet will be allowed to resume normal manufacturing and distribution from Atrium’s Hudson facility once the FDA has notified the company that it has completed all of the corrective actions required by the consent decree, and finds that the manufacturing, processing, packing, holding, and distribution of devices from Atrium are in compliance with the decree, the FD&C Act, and the QS, MDR, and CR regulations.

The consent decree also requires Maquet and its related companies to retain third-party experts to conduct inspections or audits and to help develop and implement plans to correct the violations found by the agency. The FDA will monitor the progress of the companies and their implementation of corrective actions through review of the third-party expert reports and its own inspections.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety and effectiveness of human and veterinary drugs, biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- **FDA Warning Letter to Maquet Cardiopulmonary AG (/ICECI/EnforcementActions/WarningLetters/2014/ucm426977.htm)**
- **FDA Warning Letter to Maquet Cardiovascular, LLC (/ICECI/EnforcementActions/WarningLetters/2010/ucm225051.htm)** [ARCHIVED]