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FDA bars Michigan firm from selling heart machines

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(AP) -- The federal government is legally barring a Michigan company from selling life-sustaining devices used in heart surgery, following years of quality control problems at company facilities.

The Food and Drug Administration said Tuesday it signed a permanent injunction with Terumo Cardiovascular Systems and two executives that bars them from making and distributing heart-lung bypass systems and similar machines to new customers. The devices are used to circulate blood during chest surgery.

Terumo agreed to pay $35 million in back profits from the sale of its devices and additional fines if it doesn't comply with the government's terms.

The legal document finalizing the agreement will be filed in the U.S. District Court for the Eastern District of Michigan by the U.S. Department of Justice.

Last March, FDA inspectors reported more than a dozen quality control violations at the company's plant in Ann Arbor. The problems involved company procedures for dealing with defective products, customer complaints and product design. The FDA cited Terumo for similar problems in 2004 and 2006.

The FDA said it is not recalling Terumo's products from the market because of concerns about a shortage of the machines. Additionally, the

company will be allowed to service and replace existing machines.

The company said in a statement it is already working to fix the issues.

"Over the past year, Terumo has already begun implementing a significant quality system initiative that will create systemic, sustainable improvements in its quality systems," said Mark Sutter, president and chief executive of Terumo Cardiovascular Systems.

Terumo Cardiovascular is subsidiary of Terumo Corp., which is headquartered in Tokyo.

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