The U.S. Food and Drug Administration on Friday stopped a Salt Lake-based design and manufacturing plant owned by one of the nation's largest company's from selling surgical imaging systems that could put patients at risk.

GE OEC Medical Systems ceased shipping its fluoroscopic X-ray and navigation systems last September after audits revealed numerous violations of federal quality assurance regulations. About 30 employees went on furlough.

On Friday, the FDA announced a consent decree with the company, a subsidiary of global giant General Electric, prohibiting it from making and distributing the equipment until it complies with federal law. GE OEC Medical Systems is part of the GE Healthcare division. The decree, which serves as a permanent injunction, was filed in U.S. District Court for Utah. A GE Healthcare plant in Lawrence, Mass., also is part of the decree.

"These devices are used on thousands of patients, and their dependability and accuracy are critical for the successful outcomes of important medical procedures," according to Daniel Schulz, director of the FDA's Center for Devices and Radiological Health.

GE Healthcare previously recalled its C-arm X-ray machines that, if used in a certain mode, could expose patients to excessive radiation. In addition, the machines could lose or mix up patient images after a procedure. There also may be errors in one instrument's navigational accuracy. Doctors commonly use the devices in minimally invasive orthopedic, cardiac, vascular and urological surgery to help them see inside the body.

The FDA categorizes the recalls as Class II, meaning "there is either a possibility that the device will cause temporary or reversible health problems, or there is a remote chance that the device will cause serious health problems." It does not require the equipment to be pulled from hospitals.

"This is the first time I've seen such a large recall," said Pete Jenkins, a University Hospital physicist who maintains such systems. "This is the first time I've seen the FDA restrict a company."

A consent decree is the FDA's toughest enforcement tool short of federal court seizure orders. It typically includes steps to bring a firm into compliance, a monetary fine and penalties for noncompliance. There was not a fine in this case.
"That facility has some serious problems. The FDA is breathing down their neck. Things don't look good for them," a source who requested anonymity told the Deseret Morning News.

Among the steps GE Healthcare must take is the hiring of an independent expert to inspect the Utah and Massachusetts facilities to ensure corrective measures are taken.

"The company takes FDA observations very seriously and is working aggressively to address and resolve the issues identified as quickly as possible," said to GE Healthcare spokesman Brian McKaig.

The FDA issued GE OEC Medical Systems, 384 Wright Brothers Drive, a warning letter in March 2005 after an audit revealed serious quality control lapses in manufacturing, packing, storage and installation of its equipment.

For example, the inspection showed that test technicians for more than a year photocopied results from one device to another rather than create new documents for each device. It also revealed failure to timely report equipment malfunctions "likely to cause or contribute to a death or injury if the malfunction were to recur."

A follow-up audit last August showed the company still wasn't in compliance with FDA quality-assurance requirements. Upper management had ignored internal pleas for money and personnel to correct the deficiencies identified in the FDA audits, sources told the Deseret Morning News.

In a statement, Pete McCabe, president and CEO, Surgery, GE OEC Medical Systems, said the company is committed to making safe products and following FDA rules. "Patient safety and quality continue to be our top priorities," he said in a company statement.

In a November letter to customers, GE Healthcare president and CEO Pete McCabe noted the company's equipment performed in some 60 million cases without serious injury or fatality. GE OEC C-arm X-ray systems are common in local hospitals. "None of the machines we have showed any of the problems that came out in the recall," Jenkins of University Hospital said. "But I've heard anecdotally that other facilities have experienced those problems."

Overexposure to radiation can only occur when the C-arm X-ray machines are set on a high-level control mode that doctors rarely use, he said. The likely result, Jenkins said, would be a skin burn, which could progress to the point of needing a skin graft.

General Electric bought OEC Medical Systems in 1999. It is part of the $15 billion GE Healthcare division with some 70 facilities worldwide. Since that time, OEC revenue more than doubled to some $500 million annually. Profit margins
have soared to 50 percent, meaning the company clears about $250 million a year. The company has a dominant 70 percent market share.