FDA: Medtronic must stop most sales of Synchromed drug pumps

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The Food and Drug Administration says Medtronic must stop most sales of its implantable drug pumps after years of uncorrected problems.

The FDA has filed a court order against Medtronic that says the medical device giant must halt most production and distribution of its Synchromed II drug pumps, which are implanted devices used to treat patients with cancer, chronic pain and severe muscle spasms.

Among other defects, some Synchromed pumps had to be recalled because they could lose battery power and fail, endangering patients. In other cases, the devices could cause patients to receive too much or too little medication.

Medtronic generally did not recommend that patients have the devices removed, unless they were proven to be failing.

The devices are surgically implanted and deliver a drug solution to the area surrounding the spinal cord. They are prescribed for patients who do not respond to oral medications or who experience severe side effects when taking them.

Medtronic said the agreement allows the company to make some drug pumps available on a limited basis to physicians. The Minneapolis-based company stressed it is not announcing any new recalls or safety alerts about its products.

"Patients with the Synchromed drug infusion system do not need to change their current course of therapy, have the pump removed, or take any other action as a result of this agreement," Medtronic said in a statement.

The FDA's consent decree was filed in the U.S. District Court of Minnesota and awaits the signature of a federal judge. The government says that Medtronic CEO Omar Ishrak and neuromodulation business chief Thomas Tefft sold medical devices that failed to meet federal manufacturing standards, enforced under the Food, Drug and Cosmetic Act.

A consent decree is a form of legal settlement in which a company agrees to court-ordered actions without admitting fault or guilt. The decree will remain in effect until the FDA determines Medtronic has fixed the problems outlined in the document.

Medtronic will be legally required to hire an outside expert to help correct the problems.

"Defendants are well aware that their practices violate the Act," states the government filing. "FDA has repeatedly warned defendants, both orally and in writing, about their violative conduct."

The FDA issued the company three warning letters about quality control and manufacturing problems at its drug pump facility in Columbia Heights, Minnesota between 2006 and 2013. FDA inspectors visited the plant five times over that period, the agency said in a Monday statement.

Medtronic plc is the world's largest medical device company, specializing in implantable pacemakers, defibrillators, drug pumps and other medical equipment. Last year the company completed a $43 billion acquisition of Ireland's Covidien. The company now has its executive

offices in Dublin, where it benefits from Ireland's lower corporate tax rates.

The settlement was announced concurrently by the FDA and the U.S. Justice Department.

Shares of Medtronic plc fell $1.40, or 1.8 percent, to close at $76.21.