FDA Approves MRI Scan-Friendly Pacemaker

MINNEAPOLIS (AP) — Medtronic Inc., the world's largest medical device company, said Tuesday it received U.S. approval for the first pacemaker designed to be safely used with MRI scanners.

Patients with the heart-pacing implants are strongly discouraged from having MRI scans because the radio waves could interfere with the functioning of their device. MRI scans use magnetic fields and radio frequencies to help diagnose cancers, heart conditions and other medical problems.

The company's REVO MRI pacemaker can be used with MRI scans on certain body parts and in certain patients, according to a statement from the FDA. The agency also said cardiologists and radiologists will have to undergo training to use the new devices.

Medtronic estimates that 200,000 pacemaker patients in the U.S. must opt out of the scans each year because of potential complications to their pacemakers, such as overheated wiring.

Medtronic said it would begin shipping the devices immediately.

Pacemakers use low-voltage electrical pulses to treat dangerously slow heart rhythms.

FDA approved the REVO MRI pacemaker based on a company study that showed no complications for patients who received the devices and underwent an MRI scan.

The FDA approval was unexpected as Medtronic is still trying to resolve a warning letter from the agency about problems at its manufacturing plant in Mounds View, Minn. Typically the FDA does not approve new devices when such warning letters are outstanding.

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