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FDA approves first MRI-safe pacemaker

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The US Food and Drug Administration on Monday approved the first pacemaker system -- produced by medical device giant Medtronic Inc. -- that can be used safely with MRI scanners.

Patients with pacemakers, which generate electrical impulses to treat irregular or stalled heart beats, have had to forgo MRI scans because of the risk of the machines' radiowaves interfering with the heart devices.

Medtronic estimates that about 200,000 US pacemaker patients opt out of MRI scans every year even though they play a critical role in making a wide range of health diagnoses.

Its Revo MRI SureScan Pacing System has a function that can be turned on before a scan in order to prepare patients for the MRI machines, which can be up to 30,000 times more powerful than the Earth's magnetic field.

The function reduces or eliminates potential MRI hazards.

J. Rod Gimbel of Cardiology Associates of East Tennessee in Knoxville said the new pacemaker was "a major technological breakthrough for patients who need access to MRI."

"Providing pacemaker patients with access to MRI allows detection and treatment of serious medical conditions such as stroke, cancer and a wide variety of important neurologic and orthopedic conditions."

Medtronic said pacemaker use is growing as the population ages, with about five million patients worldwide currently outfitted with a pacemaker or implantable cardioverter-defibrillator. MRI use also has increased, with about 30 million scans completed in 2007.

"FDA's approval of the Revo pacemaker represents an important step forward toward greater device innovation," said Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health.

"Those patients who meet the parameters for the device will be able to maintain their critical cardiac therapy while benefiting from the precise diagnostic capability of an MRI."

The FDA is requiring cardiologists and radiologists who use the system to receive appropriate training.