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Micra Transcatheter Pacing System approved to treat heart rhythm disorders

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The U.S. Food and Drug Administration today approved the first pacemaker that does not require the use of wired leads to provide an electrical connection between the pulse-generating device and the heart. While the Micra Transcatheter Pacing System works like other pacemakers to regulate heart rate, the self-contained, inch-long device is implanted directly in the right ventricle chamber of the heart.

Pacemakers are surgically implanted medical devices that generate electrical impulses to treat irregular or stalled heart beats, and nearly 1 million people worldwide are implanted with pacemakers each year. The leads in a traditional single chamber pacemaker run from the pacemaker, implanted under the skin near the collarbone, through a vein directly into the heart's right ventricle; the leads deliver electric pulses from the generator to the right ventricle and help coordinate timing of the chamber's contractions. Micra eliminates these leads, which can sometimes malfunction or cause problems when infections develop in the surrounding tissue, requiring a surgical procedure to replace the device.

"As the first leadless pacemaker, Micra offers a new option for patients considering a single chamber pacemaker device, which may help prevent problems associated with the wired leads," said William Maisel, M.D., M.P.H., acting director of the Office of Device Evaluation at the FDA's Center for Devices and Radiological Health. Micra is intended for patients with a heart arrhythmia called atrial fibrillation or those who have other dangerous arrhythmias, such as bradycardia-tachycardia syndrome.

The FDA evaluated data from a clinical trial of 719 patients implanted with the Micra device, which found that 98 percent of patients in the trial had adequate heart pacing (known as pacing capture threshold) six months after the device was implanted. Complications occurred in fewer than 7 percent of participants in the clinical trials and included prolonged hospitalizations, blood clots in the legs (deep vein thrombosis) and lungs (pulmonary embolism), heart injury, device dislocation and heart attacks.

Micra is contraindicated for patients who have implanted devices that would interfere with the pacemaker, who are severely obese, or who have an intolerance to materials in the device or the blood thinner heparin. It is also contraindicated for patients with veins that are unable to accommodate the 7.8 millimeter introducer sheath or pacemaker implant.

The Micra device is manufactured by Medtronic, located in Mounds View, Minnesota.

Source:
http://www.fda.gov
