MedicalXpress

New heart failure device is approved

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(HealthDay)—The Optimizer Smart System has been approved by the U.S. Food and Drug Administration for people with chronic, moderate-to-severe heart failure who are not candidates for other heart failure remedies.

"Patients with moderate-to-severe chronic heart failure have limited treatment options. And for those who are unable to be treated due to underlying conditions or who have not responded to available treatments, their quality of life may be impacted, with limits on the types of physical activities they can do," said Dr. Bram Zuckerman, director of the agency's Division of Cardiovascular Devices.

Some 5.7 million people in the United States have heart failure, which occurs when the heart cannot pump enough blood. The prime causes are conditions that damage the heart, such as high blood pressure and diabetes, the FDA said Thursday in a news release.

The new system includes an implantable pulse generator, battery charger programmer and software. The pulse generator is implanted under the skin in the upper left or right area of the chest and is connected to three leads that are implanted in the heart. After the device is implanted, it delivers electrical impulses to the heart to help improve the organ's pumping capability.

The device was evaluated in clinical studies involving 389 people with moderate-to-severe heart failure. Those given the implant showed improvements in the distance they were able to walk and on standard

assessments to measure heart failure symptoms, the FDA said.

Candidates for the system should have a regular heart rhythm, not be eligible for cardiac resynchronization therapy and have a left ventricular ejection fraction (the total amount of blood pumped out in each heartbeat) of 25 to 45 percent, which is below the normal ejection fraction of 55 to 75 percent.

Potential complications include infection, bleeding, worsening heart failure and fracture of the leads implanted in the heart.

The device is produced by Impulse Dynamics, based in Mt. Laurel, NJ.

More information: To learn more, visit the FDA.