FDA approves brain stimulation device for Parkinson's disease

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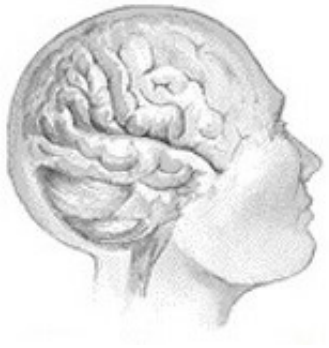

Brio Neurostimulation System is second such device approved for tremor disorders.

(HealthDay)—The U.S. Food and Drug Administration on Friday approved a device that can be implanted into the brain to help people battling Parkinson's disease.

The Brio Neurostimulation System is "an implantable deep brain stimulation device to help reduce the symptoms of Parkinson's disease and essential tremor, a movement disorder that is one of the most common causes of tremors," the FDA said in a news release.

The agency estimates that about 50,000 Americans are diagnosed with Parkinson's annually, while essential tremor affects "several million" people, most over the age of 40.

"There are no cures for Parkinson's disease or essential tremor, but finding better ways to manage symptoms is essential for patients," Dr. William Maisel, acting director of the Office of Device Evaluation at the FDA's Center for Devices and Radiological Health, said in the news release.

"This new device adds to the array of treatment options to help people living with Parkinson's and essential tremor enjoy better, more productive lives," he said.

The device is consists of a small, rechargeable battery-powered "pulse generator" implanted under the skin. Wire leads from the generator lead to specific brain locations, depending on the illness under treatment. People trained in using the devices can adjust the pulse generator's effects as needed, the FDA said.

The Brio Neurostimulation System was approved based on the results of two clinical trials, one involving 136 patients with Parkinson's disease who used the device for three months, and another involving 127 patients with essential tremor who used it for six months. In both studies, medications had already failed to control patients' symptoms, the FDA said.

"Both groups showed statistically significant improvement on their primary effectiveness endpoint when the device was turned on, compared to when it was turned off," the agency said.

The device does not come without risk, including intracranial bleeding which can lead to stroke, paralysis or death, the FDA said. Infection and device dislocation are also potential risks.

"Brio Neurostimulation System is the second device approved by the FDA for Parkinson's and essential tremor," the agency said. "The first device, Medtronic's Activa Deep Brain Stimulation Therapy System, was approved in 1997 for tremor associated with essential tremor and Parkinson's disease. In 2002, the indications were expanded to include the symptoms of Parkinson's disease."

More information: There's more on Parkinson's disease at the National Parkinson's Foundation.