FDA panel to consider brain stimulator for epilepsy

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Implantable device pre-empts seizures, device maker says.

(HealthDay News) - A U.S. Food and Drug Administration advisory panel will weigh on Friday the merits of a new therapy for some people with epilepsy who have seizures that don't respond to medication.

Smaller and thinner than an implantable defibrillator, the battery-powered, programmable device, called the RNS System, is placed just under the skull during surgery. Electrodes reach from the device to the one or two places in the patient's brain that create the abnormal electrical activity that causes seizures. The device works by short-circuiting nerve cells in that area to normalize brain activity before a seizure is triggered.

"This is the first responsive neuro-stimulation system ever designed," said Frank Fischer, president and CEO of Mountain View Calif.-based NeuroPace Inc., which developed the device. "Our long-term results show that patients have a reduction of 50 percent or more in their seizure frequency, compared to baseline, and a lessening of seizure severity."

The device is designed specifically for people aged 18 and older with partial-onset epilepsy, which occurs when one or more fixed locations in a person's brain start the cascade of nerve firing that creates a seizure.

NeuroPace has done two studies involving a total of 256 patients who were monitored for a period of between two and nine years, without any significant problems, according to Fischer.

Epilepsy is a brain disorder in which a person suffers repeated seizures over time.

It affects more than 2 million Americans, according to the Epilepsy Foundation, making it the third most common neurological disorder in the United States, after Alzheimer's and stroke. Seizures are episodes of disturbed brain activity that cause changes in attention or behavior. Brain cells keep firing instead of acting in an organized way. The malfunctioning electrical system of the brain causes surges of energy that can cause a person to have muscle contractions or to black out.

Physicians can modify the programming of the device even after it has been implanted, to reflect a patient's needs over time, Fischer said. They can also observe the brain activity of a patient from a laptop computer in their office—to help them manage a patient's treatment, he said.

On Friday, members of the FDA panel will listen to a presentation by NeuroPace and hear from members of the public; they will also ask specific questions of company officials.

By the end of the day, the panel is expected to vote on whether to recommend that the device be approved. The FDA does not have to follow the recommendations of its expert panels, but it typically does.

Representatives of the Epilepsy Foundation will also comment on the

need for innovative treatments for the disease, but they will not speak for or against approval of the product.

"We're not in a position to evaluate everything that an evaluating committee would be looking at, but we do advocate for access to treatments once they're FDA-approved," explained Angela Ostrom, vice president of public policy and advocacy for the Epilepsy Foundation, based in Landover, Md.

While Fischer said it is too soon to say what the device might cost, comparable systems for heart problems range in price from $30,000 to $35,000, not including the cost of the surgery to implant the device. The battery that powers the device lasts about three years. When it fails, a new device has to be substituted in a 30-to-60-minute outpatient surgical procedure, Fischer said.

Fischer said the company has spent 15 years developing the device.

More information: For more on epilepsy, see the Epilepsy Foundation .