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AUG 29 2005

Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

The attached application for patent term extension of U.S. Patent No. 5,299,569 was filed on July 18, 2005, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, VNS Therapy System, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. We request the assistance of your Office to confirm that the VNS Therapy System as a long-term adjunctive therapy for treatment resistant depression approved for Applicant, Cyberonics, Inc., on July 15, 2005, is the first commercial marketing or use of the product in light of the approval on July 16, 1997, of Cyberonic's NeuroCybernetic Prosthesis System for use in the treatment of epilepsy. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to Mary C. Till at (571) 272-7755 (telephone) or (571)273-7755 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Jason C. Abair
HOWREY, LLP
1111 Louisiana St., 25th Floor
Houston, Texas 77002

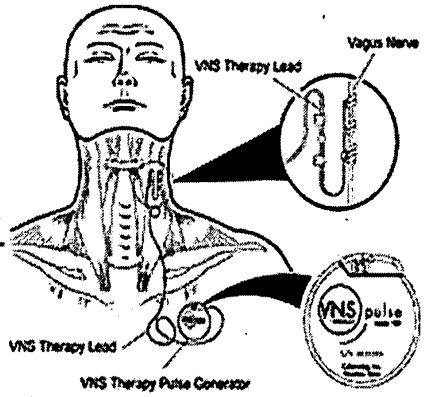
Enclosure: New Device Approval for VNS Therapy System-P970003s050 at www.fda.gov/cdrh/mda/docs/p970003s050.html.

CDRH Consumer Information

New Device Approval

VNS Therapy System - P970003s050

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.



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Product Name: VNS Therapy System
Manufacturer: Cyberonics, Inc.
Address: 100 Cyberonics Blvd., Houston, TX 77058
Approval Date: July 15, 2005
Approval Letter: http://www.fda.gov/cdrh/pdf/p970003s050a.pdf

What is it? The device is a totally implanted vagus nerve stimulator for the adjunctive long-term treatment of chronic or recurrent depression.

The device was initially approved in 1997 for epilepsy.

How does it work? A pulse generator (IPG) is implanted in the left chest and a lead (wire) is connected to the IPG and attached to the left vagus nerve. Electrical signals are sent from the IPG to the vagus nerve via the lead. To turn the stimulator off, the patient holds a magnet over the pulse generator.

When is it used? It is only to be used in patients with severe depression who are unresponsive to standard psychiatric management. It should only be prescribed and monitored by physicians who have specific training and expertise in the management of treatment-resistant depression and the use of this device. It should only be implanted by physicians who are trained in surgery of the carotid sheath and have received specific training in the implantation of this device.

What will it accomplish? The VNS Therapy System is intended to reduce symptoms of depression.

When should it not be used? It cannot be used in patients who have had a bilateral or left vagus nerve cut or who will be exposed to diathermy.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p970003s050.html

Updated July 18, 2005

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