K092364

510(k) SUMMARY

Submitted by: Karen Stueber, Domestic Regulatory Specialist
Cyberonics, Inc.
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Houston TX 77058
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NOV - 3 2009

Date of Summary: July 31, 2009

Trade Name:	Cyberonics Patient Magnet, Models 220-3 & 220-4 Cyberonics Block Magnet, Model 220-1 Cyberonics Horseshoe Magnet, Model 220-2
Common/Usual Name:	Patient Magnet
Classification Name:	Pacemaker Test Magnet
Regulation Number:	21 CFR 870.3690
Devices Class:	Class I
Product Code:	DTG

Intended Use:
The patient magnets shall be able to close the reed switch of a pulse generator when held above the reed switch, 1 inch from the generator's surface and oriented with the magnet's axis parallel to the longitudinal axis of the reed switch.

Predicate Devices:
Pacesetter Systems, Pacemaker Test Magnet (K813153)

Substantial Equivalence:
The Model 220 Patient Magnet is similar with respect to intended use and materials to the above 510(k) cleared predicate device.

Device Description
The patient magnet is used daily to check that the pulse generator battery is working. When you pass or hold the magnet over the pulse generator, a reed switch inside the pulse generator closes like a gate. When the magnet closes the switch, the normal signal (stimulation) cannot pass, and the pulse generator is temporarily turned OFF. When the magnet is removed, the switch (gate) opens immediately, and the pulse generator is turned back ON and can stimulate again.

The patient magnets are made from Neodymium grade 35 (NdFeB-35) and the entire surface of the magnet is coated with either polypropylene copolymer. The magnet is 1.48 in. x 1.05 in. x 0.195 in; 50 gauss (G) minimum magnetic flux density at a distance of 1 inch from its surface. Also supplied with Patient Magnet, are a watchband and a belt-clip that allows that patient to wear the magnet on the wrist like a watch or clipped on belt like a pager for easy deployment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV - 3 2009

Cyberonics, Inc.
c/o Ms. Karen B. Stueber
Domestic Regulatory Specialist
100 Cyberonics Road
Houston, TX 77058

Re: K092364
Trade/Device Name: Model 220, Patient Magnet
Regulation Number: 21 CFR 870.3690
Regulation Name: Patient Magnet
Regulatory Class: Class I
Product Code: DTG
Dated: August 03, 2009
Received: August 05, 2009

Dear Ms. Stueber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

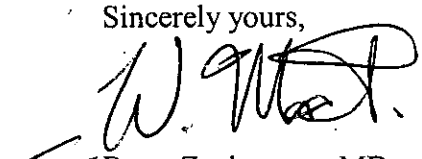
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092364

Device Name: VNS Therapy Model 220 Patient Magnet

Indications for Use:

The patient magnet is used to close the reed switch of a pulse generator when held above the reed switch, 1 inch from the generator's surface, and oriented with the magnet's axis parallel to the longitudinal axis of the reed switch.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K092364