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5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the GRINDCARE device is provided below.

MAR - 3 2010

Device Common Name: Biofeedback device

Device Proprietary Name: GRINDCARE

Submitter:
Medotech A/S
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Contact:
Calley Herzog
Consultant
Biologics Consulting Group, Inc.
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Classification Regulation:
21 CFR 890.1375 Diagnostic Electromyograph, Class II
21 CFR 882.5050 Biofeedback device, Class II
21 CFR 890.5850 Powered Muscle Stimulator, Class II

Panel:
Dental
Neurology
Physical Medicine

Product Code:
NUW: Stimulator, Muscle, Powered, Dental
KZM: Device, Muscle Monitoring, Dental
HCC: Device, Biofeedback

Indication for Use:

The GRINDCARE device is indicated to aid in the evaluation and management of nocturnal bruxism by reducing the temporalis muscle EMG activity during sleep.

Device Description:

GRINDCARE is a portable electromyographic (EMG) and electrical stimulation device. The device consists of a stimulator, a docking station and a tri-polar electrode.

The electrode is placed on the forehead with three integrated electrodes in close connection to the temporalis muscle by means of a double-adhesive patch incorporating three conductive gelpads and connected to the stimulator. The device records EMG activity and processes the signal to detect a particular activity (tooth grinding/clenching). It uses EMG to sense contraction of the temporalis muscle that is associated with bruxing events. In response to the EMG-measured contraction, it delivers mild electrical stimulation that is intended to relax the muscle and inhibit the bruxing event. The EMG events are logged and stored on the device. This data can be transferred to a healthcare professional's PC for assessment of the user's bruxism.

Performance Data:
Device testing was performed and the device was shown to meet its design specifications.

Device performance will also be in conformance to the following standards prior to marketing:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601—2-10: Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Nerve and Muscle Stimulators
- IEC 60601-2-40: Medical Electrical Equipment - Part 2-40: Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment

RF function of the device meets requirements of FCC CFR 47 Part 15, Subpart C. Clinical data are provided to demonstrate safety and effectiveness, and therefore, substantial equivalence of the GRINDCARE device for the proposed indication for use.

Substantial Equivalence:
The GRINDCARE device is a biofeedback device that is intended to aid in the evaluation and management of nocturnal bruxism by reducing the temporalis muscle EMG activity during sleep. It uses EMG to sense contraction of the temporalis

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muscle that is associated with bruxing events. In response to the EMG-measured contraction, it delivers mild electrical stimulation that is intended to relax the muscle and inhibit the bruxing event.

GRINDCARE is substantially equivalent to the following predicate devices:

- SLP, Inc Bitestrip (K030869)
- Myotronics Noromed Model J-5 Myomonitor (K031998)
- Cole and Associates Mentamove (K040849)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medotech A/S
C/O Ms. Calley Herzog
Consultant
Biologics Consulting Group, Incorporated
13417 Quivas Street
Westminster, Colorado 80234

MAR - 3 2010

Re: K092675
Trade/Device Name: Grindcare
Regulation Number: 21CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: II
Product Code: HCC
Dated: February 24, 2010
Received: February 26, 2010

Dear Ms. Herzog:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

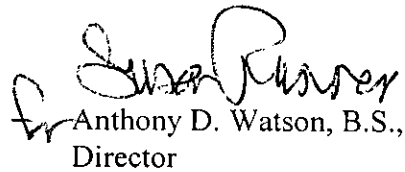
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4.0 Indications for Use Statement

510(k) Number (if known):_____

Device Name: GRINDCARE

Indications For Use:

The GRINDCARE device is indicated to aid in the evaluation and management of nocturnal bruxism by reducing the temporalis muscle EMG activity during sleep.

Prescription Use __X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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