K061705

# 510(k) Summary

**Submitter:** Cadwell Laboratories, Inc.

**Contact Person:**
Chris Bolkan
Safety / Regulatory Specialist
Cadwell Laboratories, Inc.
909 N. Kellogg Street
Kennewick, Washington 99336

NOV 2 1 2006

**Date Prepared:** May 22, 2006

**Trade Name:** EasyNet® Nasal Pressure Module

**Classification Name And Number:** Class II, 21 CFR 868.2375

**Product Code:** MNR

**Classification Panel:** Anesthesiology

**Predicate Device:** Pro-Tech PTAF 2 Nasal Pressure Sensor, K982293

**Device Description:** The Cadwell EasyNet® Nasal Pressure Module provides respiratory airflow data to Cadwell EasyNet® enabled systems. It outputs a digital representation of the data using the Cadwell proprietary EasyNet® communications protocol. The module measures 2 x 1.4 x .8 inches. It weighs about an ounce and is attached to the patient's chest or shoulder with elastic straps. An oral/nasal cannula is attached from the module to a patient's nose and mouth. A single small cable connects the device to the EasyNet® enabled system. The module requires no routine calibration or maintenance.

The Nasal Pressure module determines functional respiratory airflow by recording pressure changes at the nose and mouth.

**Indications for Use:** The Cadwell EasyNet Nasal Pressure Module collects respiratory airflow data for adult and pediatric patients. The data is transmitted to a Cadwell EasyNet enabled system where it is displayed. The module may be used in a hospital, clinical or ambulatory setting for EEG studies, sleep disorder studies and other neuromonitoring and neurodiagnostic studies.

**Functional and Safety Testing:**

Cadwell's EasyNet® Nasal Pressure Module has been tested both in a development environment and in a clinical setting with human subjects to support the determination of substantial equivalence and confirm conformance to accuracy and precision specifications.

**Conclusion:**

Cadwell's EasyNet® Nasal Airflow Module is substantially equivalent to the predicate device in terms of safety, accuracy, functional design and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Chris Bolkan
Product Safety/Regulatory Specialist
Cadwell Laboratories, Incorporated
909 North Kellogg Street
Kennewick, Washington 99336

NOV 21 2006

Re: K061705
Trade/Device Name: Cadwell EasyNet Nasal Pressure Module
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: October 10, 2006
Received: October 27, 2006

Dear Mr. Bolkan:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number: K061705

Device Name: Cadwell EasyNet Nasal Pressure Module

Indications for use: The Cadwell EasyNet Nasal Pressure Module collects respiratory airflow data for adult and pediatric patients. The data is transmitted to a Cadwell EasyNet enabled system where it is displayed. The module may be used in a hospital, clinical or ambulatory setting for EEG studies, sleep disorder studies and other neuromonitoring and neurodiagnostic studies.

Contraindications: No absolute contraindications

Precautions: This product is for diagnostic purposes only and is not to be used in a life supporting or life-sustaining situation.

Warnings: The EasyNet Nasal Pressure Module is NOT sealed against the ingress of fluids. Do not bathe while wearing the module. Do not use if wet.

Not for use in the presence of explosive atmosphere or flammable anesthetics

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K061705