K041724

Medcare

SEP 2 8 2004

510(k) Summary

Submitter

Medcare Flaga
Sidumuli 24
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Contact person

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Preparation Date

June 17, 2004

Device

Trade Name:	Compass M10 system
Classification Name:	Ventilatory Effort Recorder
Regulation Number:	868.2375
Product Code:	MNR
Device Class:	Class II
Classification Panel:	Anesthesiology

Predicate Devices

Embla N7000 from Medcare Flaga
Product Code: MNR
510(k) Number: K024322

Rembrandt System from Medcare Flaga
Product Code: FLS
510(k) Number: K962865

ApLab from Sector Medical Corp.
Product Code: MNR
510(k) Number: K030379

Device Description

The Compass M10 system is an ambulatory recording system. It includes a recording device, a signal adapter, respiratory effort sensors, strap system for attaching of recording device to a patient, an USB cable for data download and the Compass application.

The Compass M10 device is a pocket size battery powered digital recorder that incorporates electronics to record and store one night of physiological parameters. It has two respiratory channels for measurement of thoracic and abdominal movements and a built-in body position and actigraph sensor for measurement of body position and movement. It also has an optional oximeter input to measure degree of oxygen saturation of the blood.
The Compass application provides the means to prepare the device for recording, download the recorded data, viewing and analyzing the recorded data on a PC.

Intended Use

The intended use of the Compass M10 system is to record physiological signals during sleep, scan the signals for abnormalities and represent the count of abnormal events in a form of a summary report. The results of the scan may be manually overwritten or corrected by the physician. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's count of abnormal events. It is not intended for any diagnosis. It is not intended to be a monitor.

The Compass M10 system is intended to be used for adult and pediatric patients.

Technological Characteristics

The comparison table is provided as a summary of the technological characteristics relative to the predicate devices. The summary demonstrates that the Compass M10 system has no significant differences from the predicate devices that would adversely affect product safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2004

Mr. Berglind Hallgrímsdóttir
Quality Manager
Medcare Flaga
Sidumuli 24
108 Reykjavik
Iceland
EUROPE

Re: K041724
Trade/Device Name: Compass M10 System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: September 10, 2004
Received: September 15, 2004

Dear Mr. Hallgrímsdóttir:

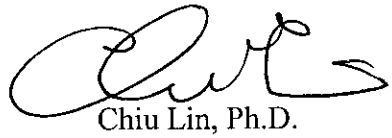
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indication for Use

510(k) Number (if known): K041724

Device Name: Compass M10 System

Indications For Use:

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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)

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

510(k) Number K041724