K041904

Medcare

SEP - 7 2004

510(k) Summary

Submitter

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Preparation Date

July 9, 2004

Device

Trade Name:	Compass F10 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 F10 system is an ambulatory recording system. It includes a recording device, a signal adapter, strap system for attaching of recording device to a patient, an USB cable for data download and the Compass application.

The Compass F10 device is a pocket size battery powered digital recorder that incorporates electronics to record and store one night of physiological parameters. It has one respiratory channel for measurement of nasal pressure/airflow 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 F10 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 F10 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 F10 system has no significant differences from the predicate devices that would adversely affect product safety and effectiveness.

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	Embla N7000 (K024322)	Rembrandt System (K962865)	ApLab (K030379)	Compass F10 system
Number of acquisition units	Three units.	No hardware.	One unit.	One unit.
Case	ABS Plastic (Patient Unit).	No hardware.	ABS Plastic.	ABS Plastic. Aluminum.
Sensor Adapter (Proxy)	Polyimide.	No hardware.	No proxy.	Polyimide.
Dimension	80mm (2.5") W, 111mm (4.9")H, 18.5mm(0.8") D (Patient Unit).	No hardware.	81.3mm (3.2") W, 68.6mm (2.7")H, 25.9mm (1.02") D.	65mm (2.5") W, 124mm (4.9")H, 20mm(0.8") D.
Weight	280g (Patient Unit).	No hardware.	90.7g.	100g.
Power Source	115/230V AC	No hardware.	3V Lithium battery (Data Acquisition). Host PC (Data Transfer).	3V by 2 AA batteries (Data Acquisition). Host PC (Data Transfer).
Control	Data acquisition and data storage microprocessor controlled. Acquisition parameters set from application SW.	Acquisition parameters set in application SW.	Data acquisition and data storage microprocessor controlled.	Data acquisition and data storage microprocessor controlled. Acquisition parameters set from application SW.
Data Interface	Ethernet.	No hardware.	USB v1.1.	USB v1.1.
Patient isolation	Isolation between mains and applied part.	No patient connection.	Device has no galvanic connections to mains as it is a battery operated device. Not possible to connect auxiliary devices to the device.	Device has no galvanic connections to mains as it is a battery operated device. Not possible to connect auxiliary devices to the device.
Method of Connection to Patient	Elastic cloth material for support of device. RIP belts for respiratory effort. Probes or Flexi Wrap for oximetry. Plastic tubing and cannula for pressure sensing. Touch proof electrode cables. Thermistor. Snore Sensor. Piezo belts for respiratory effort.	No patient connection.	Elastic cloth material for support of device. Plastic tubing and cannula for pressure sensing.	Elastic cloth material for support of device. Probes or Flexi Wrap for oximetry. Plastic tubing and cannula for pressure sensing.

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	Embla N7000 (K024322)	Rembrandt System (K962865)	ApLab (K030379)	Compass F10 system
Single use	Disposable XactTrace Belts. Flexi Wrap disposable. Plastic cannula disposable. Remaining portions require cleaning.	No hardware.	Plastic cannula and filter disposable. Remaining portions require cleaning.	Flexi Wrap disposable. Plastic cannula disposable. Remaining portions require cleaning.
Number of channels	Seven channels (Patient Unit). 40 channels (Bedside Unit). Eight auxiliary channels (Communication Unit).	8-64 channels.	One Channel.	Four channels.
Signals recorded	Respiratory Effort (Abdomen and Thorax). Body position. Activity. Oxygen Saturation. Pulse Nasal pressure. Airflow. Snore. EEG, EOG, EMG, ECG.	Respiratory Effort (Abdomen and Thorax). Body position. Activity. Oxygen Saturation. Pulse Nasal pressure. Airflow. Snore. EEG, EOG, EMG, ECG. Leg movement. Upper airway resistance. Body temperature. Video.	Nasal Pressure.	Body position. Activity. Oxygen Saturation. Pulse. Nasal Pressure.
Sensor Technology used in/with the system	Solid state pressure sensor. Solid state position/activity sensor. Respiratory Effort sensors based on respiratory inductive plethysmography. Oximetry. Thermistor. Piezo snoring sensor. Gold cup electrodes. Ag/AgCL electrodes. Piezobelts for respiratory effort.	No hardware.	Solid state pressure sensor.	Solid state pressure sensor. Solid state position/activity sensor. Oximetry.
Data validation	On-line in the application SW (not a part of the system). Status light on Bedside Unit.	On-line in the SW.	Visual verification of operating condition by light indicator on device.	Visual verification of the respiratory signals by light indicators on device.
Operating System	No software application.	Microsoft Windows NT and 95.	Microsoft Windows ™ 2000 and XP.	Microsoft Windows™ 2000 and XP.
Data review on screen	No software application.	Yes.	Yes.	Yes.

	Embla N7000 (K024322)	Rembrandt System (K962865)	ApLab (K030379)	Compass F10 system
Generate and print of reports	No software application.	Yes.	Yes.	Yes.
Patient data entry	No software application.	Yes.	Yes.	Yes.
Analysis	No software application.	Manual.	Automatic, result may be manipulated.	Automatic, result may be manipulated.

Testing

The Compass F10 system has been tested and verified in various phases, internal testing, verification and validation as well as external testing. The design was verified throughout the design process. Risk analysis was done, appropriate measures were implemented and their effectiveness verified. External test house, SEMKO, was used to confirm compliance to EMC requirements and standards for electrical safety.

Performance Data

The signals recorded with the Compass F10 system were compared to signals recorded with the predicate device Embla N7000 using the predicate Rembrandt software for review. The result demonstrates the reliability and usability of all signals recorded with the Compass F10 system.

The Compass automatic scoring was compared to manually scored PSG to demonstrate the safety and effectiveness of the Compass automatic analysis. The validation data used was recorded with Embla N7000 using full polysomnography (PSG). The recordings were all hand scored by the same RPSG technician. The results are summarized in the following table:

	Compass F10 + oximeter	**Compass F10 (without oximeter)**
Sensitivity	100%	96.8%
Specificity	87%	82.6%
PPV	91.2%	88.2%
NPV	100%	95.0%
Correlation	96.98%	88.59%
Bland & Altman	95% confidence interval from -6.3 to 6.1 with an average of -0.1	95% confidence interval from -14.3 to 10.6 with an average of -1.8

The result summarized in the table above demonstrate that the Compass automatic scoring gives a good estimate of AHI values compared to manually scored AHI from a full Polysomnography. The results obtained when SpO2 data is present are significantly better than when SpO2 data is not present. The Compass F10 system, when used to distinguish between Normals and potential OSA's patient, performs very well in all cases.

The above performance test results were compared to a clinical study done with the predicate ApLab. In this study the ApLab automatic scoring was compared to a manually scored PSG. The clinical result show ApLab sensitivity of 89% compared to 100% for Compass F10 system with oximeter and 96.8% for Compass F10 system without oximeter.

Conclusion

The performance tests results confirm accuracy of the recorded data and the Compass automatic scoring. Based on the extensive testing, performance data and comparison to the predicate devices, it is the conclusion of Medcare Flaga that the Compass F10 system is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2004

Mr. Berglind Hallgrimsdottir
Quality Manager
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ICELAND

Re: K041904
Trade/Device Name: Compass F10 System
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: July 9, 2004
Received: July 15, 2004

Dear Mr. Hallgrimsdottir:

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.

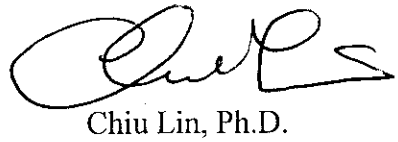
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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.
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Enclosure

Indication for Use

510(k) Number (if known): K041904

Device Name: Compass F10 System

Indications For Use:

The intended use of the Compass F10 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 F10 device is intended to be used for adult and pediatric patients.

Prescription Use ___X___ (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 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: K041904