K073682

Traditional 510(k) Notification for Embla Embletta GOLD™ Recorder

510(K) SUMMARY

AUG - 8 2008

SUBMITTER INFORMATION

A. Company Name: Embla Systems Inc.

B. Company Address: 11001 W. 120th Ave., Suite 200
Broomfield, Colorado 80021

C. Company Phone: (303) 790-1801

D. Company Facsimile: (303) 790-1810

E. Company Contact: Robert G. Schueppert
Manager, Regulatory Affairs
E-mail: bob.schueppert@embla.com

PREPARATION DATE

December 21, 2007

DEVICE IDENTIFICATION

A. Device Trade Name: Embletta GOLD

B. Device Common Name: Embletta GOLD polysomnographic recorder

C. Classification Name: Ventilatory Effort Recorder

D. Regulation Number: 21 CFR 868.2375

E. Product Code: MNR

F. Device Class: Class II

G. Classification Panel: Anesthesiology

PREDICATE DEVICES

A. Trade Name: Compass F10 System, 510(k) Number: K041904
B. Trade Name: Somté System, 510(k) Number: K021176
C. Trade Name: Medipalm – 20, 510(k) Number: K031202
D. Trade Name: Crystal 20 Monitors, 510(k) Number: K042039

DEVICE DESCRIPTION

The Embletta GOLD polysomnographic recorder is intended for both clinical and research sleep applications, with 9 input channel capability of several types of physiological signals used by a physician or trained technician for the simultaneous acquisition of respiratory, electroencephalogram (EEG), electrocardiogram (ECG, EKG), positional, user triggered event and Oximetry parameters from a patient during sleep related studies.

The device will be capable of a minimum of 24 hours of recording and saving all 9 input channels either to an internal memory or to a connected computer.

The general intended environments are hospitals, institutions, sleep centers, sleep clinics, patient homes but the device should be capable of functioning in any environment where patients can sleep reasonably comfortably.

The users are the general public, trained physicians, trained sleep technicians (RPGST) or people working under the supervision of one of these professionals. The user may or may not possess knowledge of the physiological signals or test criteria.

The recorder does not provide any alarms and is not intended to be a monitor.

A trained sleep technologist (polysomnographer) and a physician would typically review and analyze the recorded signals when downloaded and presented on a PC using a separate application software program.

INTENDED USE

The Embletta Gold is a digital recording device designed to be used under the direction of a physician or trained technician but applied by a layperson. The Embletta Gold records multiple physiological parameters for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep-related medical disorders by trained personnel. The Embletta Gold is intended to be used for adult and pediatric (excluding neonatal and infant) studies. Note the recorder is not equipped with an alarm device and is not intended to be used as a life monitor.

The intended environments include any clean, dry, dust free environment suitable for a patient's relative comfort.

COMPARISON TO PREDICATE DEVICES

The Embletta GOLD recorder is substantially equivalent in the following technological ways to the intended use and application in the identified predicate devices;

- Indications for Use
- Target population
- Basic design and architecture
- Where used
- Standards met
- Data Interface
- Signals recorded

The four predicate device data recorders, (1) the Medcare Flaga Compass F10, (2) the Compumedics Somté System, (3) the Braebon Medipalm – 20, and (4) the Cleveland Medical Devices Crystal 20 Monitor are all small palm-size portable devices that connect to one or more probes or sensors on the patient to record a variety of physiological signals. This data is then downloaded into a separate computer where the polysomnographic application software presents the signals in a format that can be read by a polysomnographic technologist or physician.

TESTING AND PERFORMANCE DATA

Safety tests have been completed to verify compliance with IEC 60601-1/UL60601-1 and all applicable particular standards in this family of international safety standards to ensure that there are no potential hazards on patients, operators, or the surroundings. The results of these tests demonstrate compliance with these safety standards.

Electromagnetic Compatibility tests according to IEC 60601-1-2 have been completed to ensure that no intolerable electro-magnetic disturbances are introduced. The results of these tests demonstrate compliance with this standard.

Immunity tests to IEC 60601-1-2 have been completed to ensure that the device operates satisfactorily in an electromagnetic environment. The results of these tests demonstrate compliance with this standard.

The internal testing, verification in various design phases, and validation of performance specifications have been completed. The results demonstrate the safety and effectiveness of the device in accordance with the intended use.

No other specific guidance document on performance is required for this type of device.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Biocompatibility and Sterilization do not apply.

CONCLUSION

The signals and channels recorded by the Embletta GOLD recorder were compared to signals and channels recorded by the predicate device recorders. The result of the comparison is that all signals recorded by the Embletta Gold are currently recorded by one or more of the predicate devices.

It is therefore the conclusion of Embla Systems Inc. that the Embletta GOLD recorder 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

Mr. Robert G. Schueppert
Manager, Regulatory Affairs
Embla Systems Incorporated
11001 West 120th Avenue, Suite 200
Broomfield, Colorado 80021

AUG - 8 2008

Re: K073682
Trade/Device Name: Embletta GOLD
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: July 28, 2008
Received: July 29, 2008

Dear Mr. Schueppert:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

July 28, 2008

STATEMENT OF INDICATIONS OF USE

510(k) Number (if known): K073682

Device Name: **Embletta GOLD**

Indications For Use:

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The Embletta Gold is intended to be used for adult and pediatric (excluding neonatal and infant) studies. Note the recorder is not equipped with an alarm device and is not intended to be used as a life monitor.

The intended environments include any clean, dry, dust free environment suitable for a patient's relative comfort.

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

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