K111742

ATTACHMENT 'C'

AUG 3 1 2011

510(K) SUMMARY

SUBMITTER INFORMATION

A. Company Name:	Embla Systems
B. Company Address:	9351 Grant St.., Suite 600 Thornton, Colorado 80229
C. Company Phone:	(303) 790-1801
D. Company Facsimile:	(303) 790-1810
E. Company Contact:	Robert G. Schueppert Director, Regulatory Affairs E-mail: bob.schueppert@embla.com

PREPARATION DATE

June 16, 2011

DEVICE IDENTIFICATION

A. Device Trade Name:	Embla N7000 with MDrive
B. Device Common Name:	Embla N7000
C. Classification Name:	Breathing Frequency Monitor
D. Regulation Number:	21 CFR 868.2375
E. Product Code:	MNR
F. Device Class:	Class II

PREDICATE DEVICES

A. Trade Name: Embla N7000, 510(k) Number: K024322

DEVICE DESCRIPTION

The original cleared N7000 system consists of 3 separate components; a mains connected Communication Unit (CU) for signal amplification and transmission to a host PC, a Headbox that is cable connected to the CU, and a Patient unit that is cable connected to the Headbox. Patient electrodes are connected to the Headbox and the Patient Unit with several electrodes and sensors non-invasively attached to a patient during sleep.

The MDrive device is intended as an alternate upgrade for the current CU component and provides all original functionality and system connectivity that exists with the CU.

The major additions that the MDrive provides over the existing CU component in the N7000 system are:

1. A wireless connection option to the host PC, in addition to a wired connection,
2. a local keypad and display for the user to perform electrode impedance checking and biocalibration locally rather that from a remote PC, and
3. study recording capability using an SD card in the event of PC host communication interruption. The SD card study can then be uploaded to the host PC.

INTENDED USE

The N7000 system (with MDrive) is intended for clinical sleep applications, with recording and/or amplification capability of numerous types of physiological signals used by a physician or trained technician for the acquisition of respiratory, electroencephalogram (EEG), electrocardiogram (ECG, EKG), positional, user triggered event and Oximetry parameters from a patient connected Headbox and/or Patient Unit during sleep related studies.

The general intended environments are hospitals, institutions, sleep centers, and sleep clinics, 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 N7000 system 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 N7000 data when it is communicated and presented on a PC using a separate application software program.

INDICATIONS FOR USE

The Embla N7000 is intended for use by a physician or trained technician for the acquisition of EEG and polysomnography (PSG) signals and transmission of these signals to a PC during neurophysiologic or sleep examinations. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.

The use of the Embla N7000 system does not involve any patient monitoring or diagnosis.

COMPARISON TO PREDICATE DEVICES

The Embla MDrive is intended as an upgrade and direct replacement for the Communications Unit in the N7000 predicate device. It is substantially equivalent to the Communications Unit in the following technological ways to the intended use and application in the N7000 system;

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

TESTING AND PERFORMANCE DATA

Safety tests on the N7000 with the MDrive have been performed to verify compliance with IEC 60601-1/UL60601-1 and any applicable particular standards in this family of international safety standards to ensure that there are no potential hazards on patients, operators, or the surroundings.

Electromagnetic Compatibility tests according to IEC 60601-1-2 have been performed to ensure that no intolerable electro-magnetic disturbances are introduced.

Immunity tests to IEC 60601-1-2 have been performed to ensure that the device operates satisfactorily in an electromagnetic environment.

The internal testing, verification in various design phases, and validation of performance specifications have been completed with acceptable results.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Biocompatibility and Sterilization do not apply.

CONCLUSION

The signals received, amplified, recorded and transmitted by the MDrive in the Embla N7000 system were compared to signals received, amplified and transmitted by the Communications Unit in the N7000 predicate system. The result of the comparison is that all signals received, amplified, recorded and transmitted by the MDrive were identical to signals received, amplified and transmitted by the predicate devices.

It is therefore the conclusion of Embla Systems that the Embla MDrive 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert G. Schueppert
Director, Regulatory Affairs
Embla Systems
9351 Grant Street, Suite 600
Thornton, Colorado 80229

AUG 31 2011

Re: K111742
Trade/Device Name: Embla N7000 with MDrive
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: July 29, 2011
Received: August 2, 2011

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. 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

SECTION 9

STATEMENT OF INDICATIONS OF USE

510(k) Number (if known): Unknown

Device Name: **Embla N7000 with MDrive**

Indications For Use:

The Embla N7000 is intended for use by a physician or trained technician for the acquisition of EEG and polysomnography (PSG) signals and transmission of these signals to a PC during neurophysiologic or sleep examinations. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.

The use of the Embla N7000 system does not involve any patient monitoring or diagnosis.

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)

L Schultheis

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

510(k) Number: K111742