K024322

OCT 27 2003

Medcare

510(k) Summary

December 19th, 2002

Submitter

Medcare Flaga
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Europe

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Device

Trade Name:	Embla N7000
Common Name:	EEG Amplifier
Classification	Electroencephalograph, Class II
Product Code	GWQ
Classification Panel	Neurology

Substantial Equivalence

Artisan™ Acquisition System For EEG and polysmnography.

Airsep Corporation

290 Creekside Drive
Buffalo, NY 14228

510(k) Number K992283

Description of the Device

The Embla N7000 system is a full polysomnography system with expanded EEG capability. It is used to perform online sleep studies in the sleep lab, hospital or clinical environment under the supervision of a clinician or sleep technician. *It does not do the recording, monitoring or analysis of this data.*

The Embla N7000 system integrates digital technology and precision engineering into a flexible, rugged, full polysomnography system. The system itself, featuring an Ethernet network connection, is simple to assemble and the cables have been streamlined to provide a comfortable and reliable system. Meeting the most demanding clinical and research needs by offering 32 referential EEG channels, 8 bipolar channels plus an extensive set of respiratory signals, the system also includes auxiliary inputs for additional devices such as CPAP and CO2 machines.

Intended Use of the device

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.

Technological Charaterics

Both Artisan and Embla N7000 are used for amplifying EEG and sleep signals in clinical and research laboratories. Both are designed for collection and transmission of sleep data to a personal computer. Both systems are only acquisition systems from amplifying and digitizing EEG and other polygraph channels and their transmission to a PC.

The amplification and data acquisition functions are similar for both systems. The main difference is the extended hardware possibilities of re-referencing in the Embla N7000. Also the Embla N7000 is controlled by software that is stored in internal Flash memory and runs on internal microprocessors. Artisans programs are also stored in internal Flash memory and run on a PLD (Programmable Logic Device). The difference between a microprocessor and a PLD is mainly how the commands are processed in each device. The software for PLDs sets up the configuration of the PLDs electronics to make it perform certain logical operations. The software for microprocessors performs the same logical operations by a sequence of instructions executed in the processors CPU. The software development was done according to the firmware development process at Medcare Flaga and it was verified that the software requirements are met. The software level of concern for both products was minor.

The patient mains-isolation is equivalent for the two devices. The N7000 has internal mains isolation transformer to power the device. The Artisan is powered from external mains transformer that provides the same isolation. In both cases the mains isolation fulfills the reinforced requirements of over 4000V manufacturing test voltage, set by the EN60601-1 and UL-2601.

The isolation from external devices is done in similar way in both devices. In Artisan, a special external box containing AD converters and opto-couplers are used to isolate the signals, but in N7000 the similar converters and opto-couplers are built in the device.

The construction of the communication isolation is also equivalent. Artisan uses fiber-optic cable for the isolation, using a proprietary communication standard for the point to point communications with the PC. The N7000 uses a signal-transformer to isolate the communications and communicates over standard Ethernet with the PC.

Test

The Embla N7000 has been tested and verified in various phases, the testing included design review, internal verification and validation as well as external testing/validation. The design was verified throughout the design process. Internal validation included bench testing and practical testing in a simulated sleep lab setting. Hazard analysis was done and appropriate measures were implemented and their effectiveness was verified. External test house, SEMKO, was used to confirm compliance to EMC requirements and standards for electrical safety including UL2601.

Testing performed and the results verify that the Embla N7000 is safe and effective for its intended use.

Compliance with guidelines and standards

Embla N/S7000 complies with the FDA "Electroencephalograph Devices Guidance for 510(k) Content, Draft Document, Version 1.0"

Embla N/S7000 is certified to carry the CE mark (CE 0413). The CE mark is a declaration that Embla N7000 is in compliance with the directive set forth by the European Union for medical devices.

Embla N/S7000 is manufactured by Medcare Flaga and the system conforms to the following standards and regulations:

Class IIa, Medical Device Directive (MDD), Annex V, "EC Directive" 93/42/EEC

EN60601-1:1990 with A1 and A12:1993, A2:1995 and A13:1996. (IEC 60601-1, 2nd ed., 1988 with A1,1991 and A2, 1995) : MEDICAL ELECTRICAL EQUIPMENT –PART 1: GENERAL REQUIREMENTS FOR SAFETY

EN60601-1-2:2001 MEDICAL ELECTRICAL EQUIPMENT –PART 1: GENERAL REQUIREMENTS FOR SAFETY - 2. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY –REQUIREMENTS AND TESTS

EN 61000-3-2:1995 and A14:2000. ELECTROMAGNETIC COMPATIBILITY (EMC) - PART 3-2: LIMITS - LIMITS FOR HARMONIC CURRENTS EMISSIONS (EQUIPMENT INPUT CURRENT UP TO AND INCLUDING16 A PER PHASE)

EN 61000-3-3:1995, ELECTROMAGNETIC COMPATIBILITY (EMC) - PART 3-3: LIMITS - LIMITATION OF VOLTAGE FLUCTUATIONS AND FLICKER IN LOW-VOLTAGE SUPPLY SYSTEMS FOR EQUIPMENT WITH RATED VOLTAGE UP TO 16 A

EN865:1997 PULSE OXIMETERS – PARTICULAR REQUIREMENTS

IEC 60601-2-25:1993 PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCARDIOGRAPHS

IEC 60601-2-26:1994 PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROENCEPHALOGRAPHS

IEC-60601-2-40:1998 PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROMYOGRAPHS AND EVOKED RESPONSE EQUIPMENT

EN60601-1-4 MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY - 4. COLLATERAL STANDARD: PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS

UL 2601-1: MEDICAL ELECTRICAL EQUIPMENT, PART 1:GENERAL REQUIREMENTS FOR SAFETY, 2nd ed.1997

CAN/CSA C22.2 No.601.1-M90 MEDICAL ELECTRICAL EQUIPMENT PART 1: GENERAL REQUIREMENTS FOR SAFETY

AS/NZS 3200.1.0: 1998 MEDICAL ELECTRICAL EQUIPMENT – GENERAL REQUIREMENTS FOR SAFETY – PARENT STANDARD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2003

Mr. Kumar Kulkarni
Medcare Flaga
c/o RTS, Incorporated
46 Loch Haven Lane
Battle Creek, MI 49015

Re: K024322
Trade/Device Name: Embla N7000
Regulation Number: 21 CFR 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: II
Product Code: MNR
Dated: July 27, 2003
Received: July 31, 2003

Dear Mr. Kulkarni:

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,

for 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

Applicant: Medare Flaga

510(k) Number (if known): K024322

Device Name: Embla N7000

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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

E Mitchell 10/24/03

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

510(k) Number: K024322