FERGUSON MEDICAL

916-342-4133
FAX: 916-343-4541

JAN 16 1998

K971813

15 October 1997

510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

A. Classification name: Electroencephalograph

Common/usual name: Electroencephalograph, EEG monitor, EEG recorder, sleep recorder, etc.

Proprietary name: Embla

B. Substantial equivalence: Healthdyne, Inc. Alice 3, (K922106), Healthdyne, Inc. Alice 4, (K971867), SensorMedics Corp. Sensormedics 4000 Series Sleep System (K915856), New England Medical Instruments, Inc. DigiTrace Home Monitoring Monitoring Computer/ELB EEG Lunch Box (K910771), New England Medical Monitoring Company DigiTrace Sleep Computer (K944833), Cadwell Laboratories, Inc. Easy Ambulatory EEG (K946094), Oxford Medilog, Inc. Medilog 9000 System (K830295), Oxford Medilog, Inc. Model 9000 Recording & Electrophysiology System (K860456), and others.

C. Device Description: The device is an EEG and physiological signs recorder.

D. Intended use: Embla is a polysomnographic system that is intended to record, display, and print

3407 Bay Avenue • Chico, California 95973 • USA

EEG and other physiological information to clinicians/physicians. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where patients require documentation of various sleep or other physiologic disorders.

E. Technological characteristics: The Embla device is a totally digital recorder utilizing 16 channels of input data. The device is available in ambulatory as well as desktop configurations.

Sincerely,
FERGUSON MEDICAL

Frank Ferguson

Frank Ferguson
Official Correspondent (FDA)

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. Frank Ferguson
Official Correspondent
Ferguson Medical
3407 Bay Avenue
Chico, California 95973

APR - 9 2012

Re: K971813
Trade/Device Name: Embla
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV
Dated (Date on orig SE ltr): October 15, 1997
Received (Date on orig SE ltr): October 20, 1997

Dear Mr. Ferguson:

This letter corrects our substantially equivalent letter of January 16, 1998.

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,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10(k) Number (If known): K971813

Device Name: Embla

Indications For Use:

Embla is a polysomnographic system that is intended to record, display, and print EEG and other physiological information to clinicians/ physicians. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where patients require documentation of various sleep or other physiological disorders.

(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 General Restorative Devices
510(k) Number K971813

Prescription Use V OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)