3/12/99

510(k) Summary K984580

Safety and effectiveness information concerning the Biosaca from Biosys AB is summarized below.

Date Prepared December 18, 1998

Applicant

BIOSYS AB (publ)
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SE-411 34 Göteborg
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Contact Anne Mari Nedevska, Technical Administration Manager

Device Name BIOSACA

Common Name Biological Signal Recorder

Classification No formal classification name or number has been assigned for devices such as the Biosaca. Stand-alone devices for the same use as the Biosaca include the following:

Panel	Product Code	Name	21 CFR
84	GWQ	Electroencephalograph	882.1400
84	GYE	Physiological telemetry system	882.1855
84	GWP	Electromyography	882.5050
84	LEL	Sleep Assessment Device	
80	FLS	Breathing frequency	868.2375
73	MNR	Ventilatory effort recorder	868.2375
74	DPS	Electrocardiography (ECG)	870.2340
74	DQA	Pulse Oximeter	870.2700
73	DRX	Electrocardiograph electrode	870.2360

Submission Correspondent

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Chester, New York 10918
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Predicate Devices Compumedics Sleep Monitoring System, Compumedics Sleep Pty. Ltd (K955841)

Embla, Flaga hf. (K971813)

Device Description The BIOSACA is a multi-functional and an ambulatory recording device. It is a portable system for the recording, monitoring, storage and transfer of up to 22 bioparameters such as brain, heart and muscle activity, eye movement, blood pressure, breathing, body movements etc. There are applications for the BIOSACA in neurological, cardiology and sleep disorder diagnoses.

Function The BIOSACA is a biological signal recorder able to receive and record up to 22 bioparameters - 16 from two headboxes, AC and/or DC, three from the pulse oximeter and three from the sensor pad.

Intended Use The intended use for the BIOSACA is to record, monitor, display, print, store and transfer bioparameters such as brain, heart and muscle activity, eye movement, blood pressure, breathing and body movements.

The BIOSACA unit is intended to be used on an Adult population and for use at home or in health care facilities. It is not intended for use as life support equipment such as vital signs monitoring in intensive care units. The unit may be used for electrocardiography, electroencephalography, electromyography, electrooculography ballistocardiography and with AC and DC sensors.

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

Biosys AB
c/o Jane B.Campbell
J. D. Campbell Associates
485 Laroe Road
Chester, New York 10918

APR - 9 2012

Re: K984580
Trade/Device Name: BIOSACA
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, DQA, GWQ, MNR
Dated (Date on orig SE ltr): December 18, 1998
Received (Date on orig SE ltr): December 23, 1998

Dear Ms. Campbell:

This letter corrects our substantially equivalent letter of March 12, 1999.

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 Kesia Alexander

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

Indications for Use Statement

510(k) Number (if known): K984580

Device Name: BIOSACA

Indications for Use:

The BIOSACA equipment is indicated for use in the recording, displaying, monitoring, printing and storage of biological and non-biological signals for sleep disorder and epilepsy investigations as well as Electroencephalography (EEG), Electrocardiography (ECG), Electromyography (EMG), Electrooculography (EOG), Ballistocardiography, etc. BIOSACA is designed for both stationary and mobile operation and may be used in either the patient's home or the hospital. Biological signals are electrical signals which can be recorded directly from the patient. Non-biological signals are recorded using indirect methods such as recording the flow of air (breathing), blood pressure, etc.

The equipment is suitable for home use as the patient needs only a minimal amount of instruction in how to use it. The system has no lights or sounds that could confuse the patient. Signals may be stored for later or may be viewed directly in real-time in the hospital, for instance. When monitoring, the operator sees the signals at the same time as they are recorded.

The Biosaca unit is intended for use on an adult population and at home or in health care facilities. It is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984580

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)