K 991446

JUL 23 1999

510(k) Summary

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

Date Prepared April 22, 1999

Applicant

BIOSYS AB (publ)
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SE-411 34 Göteborg
Telephone: +46 31 774 21 25
Fax: +46 31 13 98 54
e-mail: info@biosys.se

Contact Anne Mari Nedevska, Technical Administration Manager

Device Name BIOSACA

Common Name Biological Signal Recorder

Classification The BIOSACA has been placed into class II (Reference K984580).

Product Code	Name	21 CFR
GWQ, OLV	Electroencephalograph	882.1400

Submission Correspondent

Jane B. Campbell
J. & D. Campbell Associates, Inc.
485 LaRoe Road
Chester, New York 10918
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Predicate Devices B I O S A C A , Biosys AB (K984580)

Embla, Flaga hf. (K971813)

Device Description The BIOSACA is a multi-functional and an ambulatory recording device. It is an ambulatory 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 B I O S A C A equipment is indicated for use in the recording, displaying, monitoring, printing and storage of human bioparameters such as brain, heart and muscle activity, eye movement, breathing and body movements.

The B I O S A C A is designed for stationary, ambulatory and mobile operation and may be used in either the patient's home, the hospital or other environments, enabling patients to be investigated under as realistic conditions as possible.

The B I O S A C A unit is intended for use on an adult population. It is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

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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

APR - 9 2012

Biosys AB
c/o Ms. Jane B. Campbell
J. & D. Campbell Associates Inc.
485 LaRoe Road
Chester, New York 10918

Re: K991446
Trade/Device Name: Biosaca System, Model 800
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): April 22, 1999
Received (Date on orig SE ltr): April 26, 1999

Dear Ms. Campbell:

This letter corrects our substantially equivalent letter of July 23, 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,

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

Indications for Use Statement

510(k) Number (if known): K 991446

Device Name: BIOSACA

Indications for Use:

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The BIOSACA is designed for stationary, ambulatory and mobile operation and may be used in either the patient's home, the hospital or other environments, enabling patients to be investigated under as realistic conditions as possible.

The BIOSACA unit is intended for use on an adult population. 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 K991446

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____