510(k) Summary of Safety and Effectiveness

SACS Medical EEG Workstation A7 JUN - 7 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

A. Submitter:

SACS Medical AB
Ekonomivägen 5
SE-436 33 Askim,
Sweden

Phone: +46 31 748 49 50
Fax: +46 31 68 39 51

Contact: Sheila Ramerman, RAC
SJR Associates (regulatory consultant to SACS Medical AB

Date Prepared: April 16, 2007

B. Device Names:

Trade Name: SACS EEG Workstation A7
Common/usual Name: Electroencephalograph, EEG
Classification Name: Electroencephalograph

C. Predicate Device:

The SACS EEG Workstation A7 is substantially equivalent to the DG Nervus EEG, K964280, currently marketed by VIASYS Healthcare.

D. Device Description:

The SACS EEG Workstation A7 ("SACS A7") is a line-powered electro-encephalograph that measures and records the electrical activity in a patient's brain via electrodes placed on the patient's head. The SACS A7 System device is comprised of a flat-panel monitor, an Intel Pentium-based computer with proprietary software installed, a separate EEG amplifier, a separate photic stimulator, and a standard computer keyboard. The components can be mounted on a customer's mobile stand or cart, or on a desk or work table. A USB cable connects the computer to the EEG amplifier, which is in turn connected to patient electrodes that are applied to specified locations on the patient's head. The system is controlled by a Windows XP-based operating system. EEG results are stored either on the Workstation itself in the SACS Database on the hard drive, or on a network server. If results are stored on the SACS Server Database on a network server, they can be reviewed from any SACS Review Workstation.

E. Intended Use:

The SACS EEG Workstation A7 is intended to be used for the measurement and recording of the electrical activity in a patient's brain, using electrodes placed on the patient's head.

The SACS EEG Workstation A7 is intended for use by qualified medical personnel trained in the use of electroencephalographs.

F. Comparison with the Predicate Device:

There are no significant differences between the SACS EEG Workstation A7 and the predicate device that would adversely affect the use of the proposed device. The SACS EEG Workstation A7is substantially equivalent to the predicate device in design, function, and indications for use/intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2007

SJR Associates
% Ms. Sheila Ramerman
Consultant to SACS Medical AB
SACS Medical AB
3684 N. Shasta Loop
Eugene, Oregon 97405

Re: K071109
Trade/Device Name: SACS EEG Workstation
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: April 17, 2007
Received: April 26, 2007

Dear Ms. Ramerman:

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.

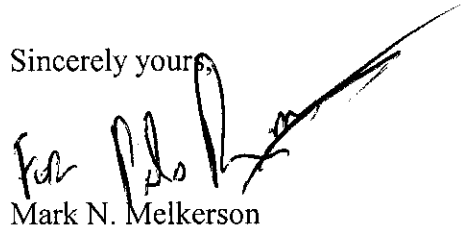
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 toll-free number (800) 638-2041 or (240) 276-3150 or at the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071109

Device Name: SACS EEG Workstation A7

Indications for Use:

The SACS EEG Workstation A7 is intended to be used for the measurement and recording of the electrical activity in a patient's brain, using electrodes placed on the patient's head.

The SACS EEG Workstation A7 is intended for use by qualified medical personnel trained in the use of electroencephalographs.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071109