K934599
1/27/94

Safety and Effectiveness Information

The SANDMAN device is used solely for the collection, storage and display of data either: a) collected by SANDMAN from FDA approved equipment that requires no modification to support this function, or b) input by the qualified technologist. The system is not directly connected to the patient and does not control any alarms, delivery of energy, drugs of any kind or functions that would effect the well being of the patient.

Safety

Since SANDMAN is connected to the output side of existing FDA approved amplifiers and only acts to replace the pen and ink recorder there is no threat to the patient's life under any conditions. We have also assessed that there are no circumstances under which SANDMAN could cause illness or permanent injury. It is not necessary to change, reconfigure or adjust the FDA amplifiers to support the SANDMAN system and SANDMAN system is configured such that it is plugged into existing output plugs designed for this purpose.

SANDMAN does not provide alarms in the case of life threatening conditions. These alarms are provided by other equipment which is not replaced by SANDMAN and is independent and unaffected by the presence, or absence, of SANDMAN. Further SANDMAN does not consolidate or obscure any information that is available in the predicate device or similar device.

Effectiveness

SANDMAN presents data on a computer monitor in a similar fashion as if the data was presented on paper. Paper printouts of the data are also available should the technologist or doctor require them. The software has no diagnostic functions although modules have been designed and validated that will identify specific data trends, defined by the operator. These trends are mathematically defined and only considered to be a tool for the use of experienced technologists. SANDMAN does not provide any information on the data or evaluate the quality of the data or any interpretation of the data. This is the sole responsibility of the experienced technologists.

SANDMAN is designed to be used by competent sleep technologists who must exercise judgement in the use of the data in the same way as they currently exercise judgement in the use of paper recording systems. All data which is collected and stored by the system has been extensively tested to ensure that the data reproduced after collection replicates that which was collected.

Through extensive testing inhouse, at beta and alpha sites, and through research studies conducted in Canada, it has been determined that following the standard calibration procedures described in the SANDMAN manual, software errors could not cause diagnostic or monitoring information to be missed or inaccurate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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Melville Software Ltd.
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CANADA

APR - 9 2012

Re: K934599
Trade/Device Name: SANDMAN Sleep EEG System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV
Dated (Date on orig SE ltr): December 1, 1993
Received (Date on orig SE ltr): December 3, 1993

Dear Mr. Anderson:

This letter corrects our substantially equivalent letter of January 27, 1994.

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