K060997

JUN 16 2006

510(k) Summary

As required by section 21 CFR 807.92(c)

Date of Submission

March 31, 2006

General Provisions

Common/Usual Name

Electroencephalograph

Proprietary Name:

Everest SNAP II

Applicant Name and Address

EVEREST BIOMEDICAL INSTRUMENTS CO.
16690 Swingley Ridge Rd.
Suite 140
Chesterfield, MO 63017

Phone: 636-519-7770 ext. 109
Fax: 636-519-7991

Contact Person:

Prepared by Randall J. Krohn

Classification

The Everest Biomedical SNAP II EEG monitor is an Electroencephalograph per 21 CFR 882.1400, which has an intended use that is consistent with the GLW classification.

Performance Standards

Performance standards for Electroencephalographs have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act after the withdrawl of "Guidance Document: Electroencephalograph Devices Draft Guidance for 510(k) Content". IEC 60601-2-26 "Particular requirements for the safety of electroencephalographs" has been followed in the development of this device per CDRH recommendations. The FDA Performance Standard for Lead Wires and Patient Cables, 21 CFR § 898, has been referenced in the preparation of this submission.

The IEC60601-1 family of electrical safety and EMC standards has been followed in the development of this device.

Predicate Device Table

Predicate	Classification(s)
Nicolet SNAP EEG Monitor (K020218)	Class II 882.1400 GWQ

Intended Use

The SNAP II is intended to monitor the state of the brain by data acquisition of EEG signals. A derived measure provided by the SNAP II, the SNAP Index, indicates the patient's brain activity level.

The SNAP II is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use, within a hospital or medical facility providing patient care.

Biocompatibility

All appropriate biocompatibility tests have been performed by the manufacturer of the electrodes and are documented in previously cleared submissions for substantially equivalent electrodes (incorporating the same patient contact materials).

No part of the SNAP II system is supplied as sterile.

Summary of Substantial Equivalence

The SNAP II is substantially equivalent in design, construction, materials, intended use and performance characteristics to the predicate devices. In vitro testing shows that the device meets similar performance specifications as those for the predicate devices. No new issues of safety or effectiveness are introduced by using this device.

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

Everest Biomedical Instruments Co.
c/o Mr. Randall J. Krohn
VP Engineering/Regulatory Affairs Manager
16690 Swingley Ridge Rd.
Suite 140
Chesterfield, MO 63017

APR - 9 2012

Re: K060997
Trade/Device Name: SNAP II EEG Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, GXY, ORT
Dated (Date on orig SE ltr): June 5, 2006
Received (Date on orig SE ltr): June 6, 2006

Dear Mr. Krohn:

This letter corrects our substantially equivalent letter of June 15, 2006.

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 (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 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

510(k) Number (if known): K060997

Device Name: SNAP II EEG Monitor

Indications for Use:

The SNAP II is intended to monitor the state of the brain by data acquisition of EEG signals. A derived measure provided by the SNAP II, the SNAP Index, indicates the patient's brain activity level.

The SNAP II is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use, within a hospital or medical facility providing patient care.

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

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