K020218

APR 2 2 2002

Summary of Safety and Effectiveness

Company Name:	Nicolet Biomedical 5225 Verona Road Madison, WI 53711
Contact: Phone: Fax:	Glen Hermanson, Manager of Standards and Compliance 608 441-2065 608 441-2007
Summary Date:	January 17, 2002
Trade Name:	SNAP
Common Name:	EEG Monitor
Classification Name:	21 CFR 882.1400; Product Code: OLW, OMC, ORT

Predicate Device(s):

510(k) Number: K952347
Manufacture: ASPECT Medical Inc.
Trade Name: A-1050 EEG Monitor

510(k) Number: K991054
Manufacture: Nicolet Biomedical
Trade Name: Bravo Endeavor Multi-Modality System

1.0 Description of Device

The SNAP device records and displays a processed EEG parameter called the SNAP Index, records and displays a time based trend of the SNAP Index and displays a real time EEG signal. The SNAP system has four significant components:

1. A Visor SNAP module, which is inserted into the springboard slot of a Handspring Visor handheld computer.
2. A disposable, single patient use SNAP Electrode for acquiring the EEG signal.
3. A patient cable which connects the Visor SNAP module to the patient electrode.

4. SNAP personal computer application software, which is provided for use on personal computers operating with Microsoft Windows® operating systems.

2.0 Intended Use

The intended use of the SNAP device is consistent with the classification 21 CFR 882.1400, Electroencephalograph:

> "An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head."

The SNAP device is intended to monitor a patient's EEG. A derived EEG measure, the SNAP Index, indicates the patient's brain activity level. The SNAP device is a prescription device used under the guidance and interpretation of a licensed medical professional.

3.0 Technological

The technology of the SNAP device is equivalent to other EEG monitoring devices. The EEG signal is acquired in analog format, digitized and presented to the user for interpretation. The SNAP device includes an EEG trended parameter of the power spectrum of the EEG signal, SNAP Index.

The SNAP device is incorporated with a handheld computer, the Visor. A custom SNAP Electrode is provided for the convenience of the user in applying three monitoring electrodes.

4.0 Conclusions

The indications, intended use and technology of the SNAP device is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

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

Nicolet Biomedical, Inc.
c/o Mr. Gary Syring
Quality and Regulatory Associates, LLC
800 Levanger Lane
Stoughton, WI 53589

APR - 9 2012

Re: K020218
Trade/Device Name: SNAP
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, ORT
Dated (Date on orig SE ltr): January 21, 2002
Received (Date on orig SE ltr): January 22, 2002

Dear Mr. Syring:

This letter corrects our substantially equivalent letter of April 22, 2002.

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

510(k) Number (if known): K020218

Device Name: SNAP

Indications For Use:

The SNAP device is intended to monitor a patient's EEG. A derived EEG measure, the SNAP Index, indicates the patient's brain activity level. The SNAP device is used under the guidance and interpretation of a licensed medical professional.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Melkerson

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

510(k) Number K020218