

NOV - 3 1999

K 991054

510(k) SUMMARY  
BRAVO MULTI-MODALITY SYSTEM

(a) INFORMATION REQUIRED FOR ALL SUMMARIES

- (1) Submitter's Name: Nicolet Biomedical Inc.  
Submitter's Address: 5225 Verona Road, Bldg. 2  
Madison, WI 53711 U.S.A.  
Submitter's Telephone Number: (608) 273-5000  
Contact Name: Douglas E. Pfrang  
Date summary was prepared: March 26, 1999
- (2) Trade or proprietary name: Bravo Multi-Modality System  
Common or usual name: Electroencephalograph (EEG)  
Evoked Potential (EP)  
Electromyograph (EMG)  
Transcranial Doppler (TCD)  
Classification name: Electroencephalograph (84GWQ)  
Evoked Potential Electrical Stimulator (84GWF)  
Evoked Potential Photic Stimulator (84GWE)  
Evoked Potential Auditory Stimulator (84GWJ)  
Electromyograph (89GWP)  
Nonfetal Ultrasonic Monitor (90JAF) | KN & OLT

(3) Identification of the legally marketed devices to which equivalence is claimed.

1. Nicolet Spirit EMG/EP (FDA Log No. K905632)
2. Nicolet Voyageur EEG (FDA Log No. K921927)
3. Nicolet/EME Trans-Scan TCD (FDA Log No. K874685)

(4) Description of the device, including an explanation of how the device functions, the scientific concepts, and the significant performance characteristics such as device design, material used, and physical properties.

The Bravo Multi-Modality System is a personal computer-based digital data recorder for continuously monitoring various types of neurological information, including:

(i) neuroelectric and neuromuscular data pertaining to the patient's central and peripheral nervous system and muscles, and (ii) neurovascular data pertaining to blood flow in the patient's brain and related blood vessels.

The intended use of this device is to record and display EEG, EMG, EP and TCD signals; and to import and display data from third-party monitoring devices, such as vital signs monitors. EEG signals are passively recorded using electrically-conductive electrodes that are placed in electrical contact with the patient's skin or nervous system. EMG and EP signals are recorded using electrically-conductive electrodes that are placed in electrical contact with the patient's skin, nervous system or muscles. EMG signals are passively recorded, while EP

signals are evoked using a light source, a sound source, or an electrical stimulator. TCD signals are actively recorded using a non-invasive ultrasound transducer that emits and records ultrasound energy. The ultrasound energy is applied externally to the skin, passes through the skin and body tissues, reflects off blood molecules moving in the blood stream, passes back through the body tissues and skin, and returns to the transducer. Movement of the blood molecules causes a frequency or "Doppler" shift in the returned ultrasound energy, which is detected and converted into a signal representing the velocity of the blood from which the ultrasound energy was reflected. Third-party monitoring devices, such as vital signs monitors, acquire and display a variety of physiological data from the patient. Importing and displaying such data is done by taking an output signal directly from such monitoring devices without any additional connections to the patient. Data obtained from the monitoring device is then displayed, analyzed or stored by the Bravo Multi-Modality System independently of how the third-party device handles the data.

- (5) Statement of the intended use, including a description of the patient populations, and diseases or conditions, that the device is intended to diagnose, treat, prevent, cure, or mitigate. If different from the predicate device, an explanation of why the differences are not critical to the intended use when the device is used as labeled.

The Bravo Multi-Modality System is intended to record and display EEG, EP, EMG and TCD data in the clinic and hospital (including the hospital room, operating room, emergency room, intensive care unit, neuro intensive care unit, critical care unit, etc.), and to import and display data from third-party monitoring devices. It is intended to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles. It differs from the predicate devices in that it contains multiple modalities in a single device, whereas each predicate device has a very limited number of modalities. Nevertheless, like the predicate devices, the Bravo Multi-Modality System is intended to involve competent human intervention before any impact on human health occurs (i.e., clinical judgment and experience must be used to check and interpret the system's output).

- (6) Comparison between the technological characteristics of the new and predicate devices, such as design, material, chemical composition, energy source, etc.

The technological characteristics of the new and predicate devices are substantially equivalent because the hardware and software in the Bravo Multi-Modality System is largely based on the predicate devices. The design, material, chemical composition, energy source, etc., are essentially unchanged. The main difference is that advances in computer technology (i.e., hardware and software) have enabled multiple software applications to run concurrently on a single computer platform, thereby making possible a single integrated system with multi-modality capabilities. Nevertheless, each modality, when compared to a predicate device of the same modality, has similar performance specifications, a similar set of user-adjustable parameters, and is designed to comply with substantially the same performance standards.

**(b) INFORMATION REQUIRED IF EQUIVALENCE IS BASED ON PERFORMANCE DATA**

**(1) Brief discussion of nonclinical tests.**

Nonclinical tests consist of various tests to verify program function, such as testing user inputs and recording various test signals. Tests are ongoing, but indicate that the device is performing as expected. Test results are summarized below in paragraph (b)(3).

**(2) Brief discussion of clinical tests including, if applicable, a description of the subjects, a discussion of safety or effectiveness data obtained, a discussion of any adverse effects or complications, and any other relevant information.**

Clinical tests will be used to validate the device's performance under simulated or actual use conditions. Because each of the individual modalities was derived from an existing product, historical data will be a primary validation tool. To provide the remaining validation, the device will be evaluated at different health care sites to solicit comments from actual users and to assess the performance of the device under actual use conditions.

**(3) Conclusions drawn from nonclinical and clinical tests that demonstrate the device is as safe and effective, and performs as well as or better than the legally marketed device(s) identified in (a)(3).**

Clinical and nonclinical results of testing the Bravo Multi-Modality System are showing that it performs substantially as expected; i.e., that it is substantially equivalent to the predicate devices in terms of safety and effectiveness.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Mr. Douglas E. Pfrang  
Director, Regulatory and Legal Affairs  
Nicolet Biomedical, Inc.  
5225 Verona Road, Building 2  
Madison, Wisconsin 53711-4495

APR - 9 2012

Re: K991054

Trade/Device Name: Bravo Multi-Modality System  
Regulation Number: 21 CFR 882.1870  
Regulation Name: Evoked response electrical stimulator  
Regulatory Class: II  
Product Code: GWF, GWQ, GWE, GWJ, OLT, JAF, IKN  
Dated (Date on orig SE ltr): August 4, 1999  
Received (Date on orig SE ltr): August 5, 1999

Dear Mr. Pfrang:

This letter corrects our substantially equivalent letter of November 3, 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,



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): K991054

Device Name: Bravo Multi-Modality System

Indications For Use:

The Bravo Multi-Modality System is intended to record and display EEG, EP, EMG and TCD data in the clinic and hospital (including the hospital room, operating room, emergency room, intensive care unit, neuro intensive care unit, critical care unit, etc.), and to import and display data from third-party monitoring devices such as vital signs monitors. It is intended to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for* Mark A. Milbrun  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991054

Prescription Use     
Per 21 CFR 801.109

OR

Over-The-Counter Use