K971331

ATTACHMENT V

JUN 25 1997

510(k) SUMMARY

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510(k) SUMMARY
NICOLET SATELLITE

(a) INFORMATION REQUIRED FOR ALL SUMMARIES

(1) Submitter's Name: Nicolet Biomedical Inc.
Submitter's Address: 5225-2 Verona Road
Madison, WI 53711 U.S.A.
Submitter's Telephone Number: (608) 273-5000
Contact Name: Douglas E. Pfrang
Date summary was prepared: April 4, 1997

(2) Trade or proprietary name: Satellite
Common or usual name: Ambulatory EEG
Classification name: Electroencephalograph (84GWQ)

(3) Identification of the legally marketed devices to which equivalence is claimed.
1. Cadwell Easy Ambulatory (FDA Log No. K946094).
2. Bio-Logic Ceegraph Traveler (FDA Log No. K954954).

(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 Satellite is a portable, battery-powered, digital electroencephalographic (EEG) data recorder that is designed to be carried in a hip belt worn by the patient. The intended use of this device is to record the patient's EEG while the patient is ambulatory or at home. Recorded EEG data is stored in a removable hard disk drive, which the medical practitioner can then remove from the data recorder and connect to a standard personal computer. The personal computer is then used to review and analyze the EEG data, generate reports, and provide longer-term storage for the EEG data. The personal computer also performs various system utility functions on the data recorder, such as programming the user-selectable parameters, and measuring the electrical impedance of the EEG electrode connections. A battery pack and charger also accompany the data recorder. These items are designed so the battery pack cannot be recharged while it is powering the data recorder, so the data recorder (which may be attached to the patient) cannot be connected to the AC-powered charger. The device is intended to complement Nicolet's existing line of EEG systems, including the Voyageur digital EEG system (K921927B) and BMSI long-term EEG monitoring system (K891405A). Neither of these devices currently provides the capability for ambulatory or at-home EEG data recording, however, both will record and playback EEG data that is similar to the data recorded by the Satellite.

(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 Satellite is intended to record EEG data while a patient is ambulatory or at home, and 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). The device does not obscure information or data that is available to the user; it does not eliminate the use of complementary information, such as patient history information, laboratory results, and other tests; it does not change the intended use of the predicate device or similar devices; it does not create new or different indications for use for the predicate device or similar devices; and, except for recording data to assist a medical practitioner in diagnosing EEG-related conditions (such as epilepsy), it does not diagnose, treat, prevent, cure, or mitigate any illness, disease or condition. Moreover, because the device primarily records EEG data for review at a later date, and therefore provides ample opportunity for the clinician to cross-check results and perform additional tests, any failure of the device to perform as intended would be extremely unlikely to significantly alter or delay the treatment of any patient, or contribute to any injury or adverse health effect.

(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 virtually identical. Each device relies on a portable battery-powered data recorder to store up to 24 hours of a patient's EEG data in a digital format onto a standard (PCMCIA-type) removable hard-disk drive. Each device is small, lightweight, and intended for ambulatory use. Each device has a similar bandwidth and channel count, a similar time- and amplitude-resolution, and a similar set of user-adjustable parameters. Each device has similar performance specifications, and is designed to comply with substantially the same voluntary performance standards.

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

(1) Brief discussion of nonclinical tests.

Nonclinical tests consisted of using the device to record EEG test data derived from actual human EEG recordings, and included examples of actual seizures, spikes, seizure-like artifacts, and non-seizure waveforms. 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 were deemed unnecessary for purposes of validating the device's ability to perform its intended use, because non-clinical tests appeared clearly superior to any clinical tests that could be developed. Nevertheless, clinical tests were performed to solicit comments

from actual users and to assess the performance of the device under actual-use conditions. There were no adverse effects or complications affecting patients, and the device performed substantially as expected.

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

Even though the predicate devices identified in (a)(3) were not available for direct comparison testing, results of testing the Satellite showed that it was substantially equivalent, in terms of safety and effectiveness, to the specifications published for the predicate devices. In addition, the nonclinical and clinical test results for the Satellite showed that it was substantially equivalent, in terms of safety and effectiveness, to much larger Nicolet EEG products, including the BMSI long-term EEG monitoring system (K891405A).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1997

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

Re: K971331
Trade Name: Satellite
Regulatory Class: II
Product Code: 84GWQ
Dated: April 7, 1997
Received: April 10, 1997

Dear Mr. Pfrang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K971331

Device Name: Satellite

Indications for Use:

The Satellite is intended to acquire EEG data from patients that are stationary or ambulatory, regardless of whether they are inside or outside a medical-care facility.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR ~~Over-The-Counter Use~~

(Optional Format 1-2-96)