K971165

NOV 12 1997

2. 510 (K) Summary

Applicant:
Neurotronics Incorporated
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Route 1 Box 543
Waldo, FL 32694

Contact person:
Jack R. Smith, Ph.D.
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Device Name: POLYSMITH

SUBSTANTIAL EQUIVALENCE

This new system, the POLYSMITH, is essentially equivalent, with the same intended use, to the Microtronics SAC system. The same individual (Dr. Jack R. Smith) designed both systems. On October 6, 1986, the FDA notified Microtronics (Re: K862527A) that their sleep-analyzing computer was determined to be substantially equivalent to devices in interstate commerce prior to May 28, 1976. Software for the processing of heart rate and respiration signals was subsequently added (FDA Ref. K863124). Microtronics was subsequently sold to Oxford Medical Instruments, and the Microtronics system is now known as the Oxford SAC system.

Device Description

POLYSMITH is a polysomnography data acquisition, analysis, display, and storage system, which accepts polysomnography data and allows the operator to view the data on the computer monitor. The device also automatically analyzes the data to determine the sleep stage for each thirty-second epoch and to detect apneas and hypopneas. The hardware consists of a personal computer with an enclosed analog-to-digital converter and a connector block for conveniently connecting the input data leads. The device is designed to input data from a polygraph that has IRIG-compatible outputs. To use all analysis capabilities, there should be at least two EEG channels, two rapid eye movement channels (electro-occulograms), a chin EMG (electromyogram), a leg EMG, an ECG, airflow, two respiratory effort channels and an oxygen saturation channel. The software, which is running under the NT operating system, will display all of the acquired data on the computer screen for reviewing and operator editing. The automated analysis feature, designed for subjects 13 years of age and older, generates multiple reports, including a sleep stage summary, describing the sleep data.

Intended Use

The device is intended for use in a sleep laboratory for the acquisition, display, storage, and analysis of polysomnography data from a polygraph with IRIG compatible outputs. The analysis features of the system are designed for subjects 13 years of age and older.

Warning:

The POLYSMITH software derives a description of a night's sleep from raw polysomnography data presented to the system. It is possible for the summary data to be incorrect for reasons including bad or missing polysomnography data, power failure, inaccurate calibration, and clinical data, to which the system has not been exposed. The POLYSMITH maintains all of the raw data. All summary data should be verified by examining the raw data on the computer monitor. The data can be viewed with the same resolution as a 10mm/sec. polygraph recording by viewing the data in the 10-second screen display mode. Since some of the sleep-staging criteria are based on specified amplitude levels, the EEG and EOG signals must be calibrated for accurate sleep staging. It is recommended that a signal with known waveform characteristics, such as a calibration signal, be included at the beginning or end of the recording as verification that the calibration was done.

Assessment of Performance Data

The device performance was compared with that of a predicate device, the Oxford SAC system. The system performance was evaluated by analyzing six all-night sleep records recorded to optical disk at the Henry Ford Sleep Diagnostic Center (HFSDC) in Detroit, Michigan and comparing the results obtained with the predicate device. In addition, the device performance was compared to human scoring, using two all-night sleep recordings, from the HFSDC, of patients with severe sleep apnea. Each recording contains two EEG channels (central and occipital), two eye channels, a chin EMG channel, a leg EMG channel, an airflow channel, and one respiratory effort channel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2 1997

Jack R. Smith, Ph.D.
Neurotronics Incorporated
4609 NW 6th Street, B-5
Gainesville, Florida 32609

Re: K971803
Polysmith
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: August 18, 1997
Received: August 20, 1997

Dear Dr. Smith:

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 requirements, 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): K971803

Device Name: Polysmith

Indications For Use:

This device is intended for use in a sleep laboratory for the acqusition, display, storage, and analysis of polysomnography data obtained from a polygraph with IRIG compatible outputs. It's purpose is to assist a qualified sleep practitioner in the diagnosis of sleep disorders in patients 13 years of age and older. To use the analysis capabilities, there must be at least two EEG channels, two rapid eye movement channels (electrooccuIograms), a chin EMG (electromyogram) channel, a leg EMG channel, an airflow channel, two respiratory effort channels, and an oxygen desaturation channel. This device is to be used only under the direction of a physician or qualified sleep technician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ad A. Carlt.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)