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510k Summary

The Summary of Safety and Effectiveness of the Crystal Monitor Model 16 reflects data available and represented at the time the submission was prepared, but caution should be exercise in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

As required by section 807.92(a), the following summary is included for the Crystal Monitor Model 16 by Cleveland Medical Devices, Inc.

Applicant: Robert N. Schmidt
Cleveland Medical Devices
11000 Cedar Avenue, Suite 130
Cleveland, Ohio 44106

Telephone: 216-791-6720
Fax: 216-791-6744

Submission Date: 11/20/01

Trade Name: Crystal Monitor Model 16
Common Name: Electroencephalograph
Classification: Class II per regulations 882.1400
Product Codes: OMC, OLV

Equivalent Devices: Crystal EEG Model 15, 510(k) No. K001110
Compumedics Siesta System, 510(k) No. K003175

Description: The Crystal Monitor Model 16 is an eight-channel, programmable, wireless data acquisition system intended to monitor and record physiological signals. Any channel can be programmed to monitor any physiological signal. Harnesses connect electrodes or sensors from the patient to the patient unit. The patient unit, worn by the patient, acquires, amplifies, and digitizes physiological signals. These signals are then transmitted by radio frequency to a computer unit connected via a serial port to a personal computer (PC). The data is then displayed in real-time and can be stored on the PC.

The Crystal Monitor Model 16 incorporates state-of-the-art wireless technology for viewing and recording physiological signals such as EEG, EKG, EMG, and EOG. This 8-channel monitor is the most unobtrusive, flexible, and convenient way of measuring and transmitting physiological signals. Subjects can now be untethered during studies while real time data is collected and displayed. The Crystal Monitor® Model 16 wireless physiological signal monitor consists of a Transmitter (also called the Patient Unit), a Receiver Assembly (a Receiver [also called the Computer Unit], receiver cable, and power supply), accessories (Universal Differential Harness, mounting band, electrolyte gel, screwdriver, batteries, and Test Pack), and a PC Operator Interface Software program.

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The Patient Unit collects signals from electrodes attached to the subject, performs analog-to-digital conversion, encoding, formatting, and transmitting of all signals. The signals are communicated using a 902-928 MHz radio transmitter. The Computer Unit receives the transmitted data packets, performs extensive error detection and correction, and then sends the data through a Receiver cable to the PC Operator interface where the data can be stored, monitored in real time, or analyzed at a later time.

The Crystal Capture program consists of several software components that allow the user to acquire, store, and view physiological data as acquired by the Crystal Monitor Transmitter. The software provides a simple graphical interface for setting up and controlling data acquisition and patient management. The Crystal Configuration Wizard allows customization of the number of input channels (1-8), ranges (micro– to millivolts), and sampling rate. Configurations can be saved allowing the user to program the Crystal Monitor for numerous applications.

Intended Use: The Crystal Monitor® Model 16 is intended for wireless monitoring and recording of physiological signals to aid in research and/or diagnostic purposes.

The device is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

Warning: Do not use in conjunction with a defibrillator.

Contraindications:

Interference may occur in the vicinity of equipment marked with the following symbol:

Frequency of Transmitter Rated Maximum Output Power of Transmitter watts	150 kHz to 80 MHz Separation Distance meters	150 kHz to 800 MHz Separation Distance meters	800 MHz to 1.04 GHz Separation Distance meters
0.01	0.4	7	14
0.1	1.1	22	44
1	3.5	70	140
10	11.1	221	443
100	35	700	1400
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Technological Characteristics: The Crystal Monitor® Model 16 is technically the same as the predicate device, Crystal-EEG Model 15 with the exception of software, labeling, and available accessories. They have the same hardware, board designs, drawings, and manufacture. These devices have a transmitter that contains a data acquisition board for acquiring, amplifying, and digitizing physiological signals. These signals are transmitter by radio frequency to a receiver connected to a computer. The physiological signals are then viewed in real-time or stored on a computer for analysis by a clinician.

The device was subjected to the following voluntary standards to ensure the efficacy and safety of thee device for its intended use:
FCC Part 15.109, Class B digital device;
FCC Part 15.249, Intentional radiator, FCC ID#N9Y0007;
IEC 60601-1-2 Medical Electrical Equipment, Part 1 General requirements for safety.
EN 61000-4-2: 1995 Electrostatic discharge immunity test;
EN 61000-4-3: 1995 Radiated, radio-frequency, electromagnetic field immunity test;
EN 61000-4-4: 1995 Electrical fast transient/burst immunity tests;
EN 61000-4-6: 1996 Immunity to conducted disturbances induced by radio-frequency fields;
EN-55011 Electromagnetic Emissions;
IEC 601-2-26 only to the requirements for environmental conditions in regards to ambient temperature range (10° to 50° C) and humidity (25 to 95%, without condensation).

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

Mr. Robert N. Schmidt
President
Cleveland Medical Devices
11000 Cedar Avenue, Suite 130
Cleveland, Ohio 44106

Re: K013863
Trade/Device Name: Crystal Monitor® Model 16
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMC, OLV
Dated (Date on orig SE ltr): November 20, 2001
Received (Date on orig SE ltr): November 21, 2001

APR - 9 2012

Dear Mr. Schmidt:

This letter corrects our substantially equivalent letter of February 19, 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): K013863

Device Name: Crystal Monitor® Model 16

Indications For Use:

The Crystal Monitor® Model 16 is intended for wireless monitoring and recording of physiological signals to aid in research and/or diagnostic purposes.

The device is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013863

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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