NOV 17 2004

510(k) SUMMARY

K042039

The Summary of Safety and Effectiveness information on the Family of Crystal 20 Monitors® is being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Cleveland Medical Devices Inc. 4415 Euclid Avenue Cleveland, Ohio 44103
Telephone **Facsimile**	(216) 791-6720 (216) 791-6739
Date	July 26, 2004
Name	Robert N. Schmidt, President
Classification	882.1400
Predicate:	Crystal Monitor Model 16, K013863 and Siesta System, K003175
Description:	The Family of Crystal 20 Monitors® are designed to monitor physiological signals such as cardiovascular, neurological, and muscular for the purpose of research and diagnostic purposes. The Crystal 20 Monitor is a device that is programmable to the type of physiological signals being monitored such as EEG, EOG, EMG, ENG, ECG, PSG, airflow, pulse oximetry, respiratory effort, temperature, blood pressure, etc. The signals are communicated between the patient module and the computer unit using wireless technology based on frequencies such as but not limited to 902-928 MHz, 2.4 – 2.484 GHZ, Wireless Medical Telemetry Bands (WMTS), 608–614 MHz, 1395–1400 MHz, or 1429–1432 MHz. The communication between the patient module and computer unit can also be wired (instead of wireless). The Family of Crystal 20 Monitors® will consist of three major components: *1. Patient Module;* *2. Computer Unit; and* *3. Interface Software* 1. The ***Patient Module*** can have up to 32 channels and the ability to either transmit only (one-way) or transmit and receive (two-way). The basic functional feature of the component is to acquire signals from commercially available electrodes / sensors that are attached to the subject, perform analog-to-digital conversion (when appropriate), encode, format, and transmit the signals to the Computer Unit. The Patient Unit will also have on-board memory capability that will permit the physiological data to be stored inside the patient unit. The Patient Module will contain no-touch connectors to enable connections to commercially available electrodes / sensors. 2. The ***Computer Unit*** will have the ability to only receive (one-way) or receive and transmit (two-way). The basic functional feature of this component is to receive data packets, performs error detection and correction, and then sends the data to the PC Operator interface where the data can be monitored in real time or stored and analyzed at a later time.

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

Cleveland Medical Devices, Inc.
c/o Mr. Robert N. Schmidt
President
4415 Euclid Avenue
Cleveland, Ohio 44103

APR - 9 2012

Re: K042039
Trade/Device Name: Family of Crystal 20 Monitors
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): November 5, 2004
Received (Date on orig SE ltr): November 8, 2004

Dear Mr. Schmidt:

This letter corrects our substantially equivalent letter of November 17, 2004.

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): K 042039

Device Name: **Family of Crystal 20 Monitors**

The various types of model versions within the Family of Crystal 20 Monitors would be as follows:

#	Wireless Model Option	Transmission Frequencies	Bands
1	CS20 – 600	608 – 614 MHz	WMTS
2	CS20 – 900	902 – 928 MHz	ISM
3	CS20 – 1300	1395 – 1400 MHz	WMTS
4	CS20 – 1400	1429 – 1432 MHz	WMTS
5	CS20 – 2400	2400 – 2484 MHz	ISM

	Hard–Wired Model Option	Operating Voltage
6	CS20 – 120	120 VAC

Indications For Use:

The Family of Crystal 20 Monitors are intended for 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K042039

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