

K970672

**510(K) SUMMARY**

MAY 22 1997

- A) Submitter's Name:** Cleveland Medical Devices Inc.
- B) Address:** 11000 Cedar Ave. Suite 439  
Cleveland, Ohio 44106
- C) Phone and Fax numbers:** Phone: (216) 791-6720  
Fax: (216) 791-6744
- D) Contact Person:** Robert N. Schmidt
- E) Preparation Date:** February 21, 1997
- F) Classification Name:** Electroencephalograph
- Common / Usual Name:** Electroencephalograph
- Proprietary Name:** Crystal-EEG™ Model 10
- Classification:** Class II
- Regulation:** 882.1400  
(a) An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.  
(B) Classification. Class II (performance standards)

- G) Substantial Equivalence:** The design concept of the Crystal-EEG Model 10 is substantially equivalent in design to:

Hambrecht Associates Multi-Channel Electroencephalographic Telemetry System

- H) Description:** The Crystal-EEG Model 10 is a mobile, intermediate range, wireless, EEG system used for measuring and transmitting bioelectric signals such as electroencephalogram (EEG). It consists of a Transmitter; a Receiver Assembly which consists of the receiver, receiver cable, and power supply; the Software; Patient Accessories consisting of EEG Electrodes, headband, battery, and battery connector; and a PC Operator Interface which consists of Operator Interface Software, Transmitter Set-up Cable, and a Personal Computer (optional).

**I) Intended Use:** The Crystal-EEG Model 10 is a mobile, intermediate range, wireless, EEG system intended to be used for measuring and transmitting bioelectric signals such as electroencephalogram (EEG). The system allows extended EEG monitoring without having the subject tethered with wires.

**J) Summary of Safety and Effectiveness of Crystal-EEG Model 10:**  
 The Summary of Safety and Effectiveness on Crystal-EEG Model 10 reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

The Crystal-EEG Model 10 is similar in operation and function to Hambrecht Associates Multi-Channel Electroencephalographic Telemetry System

	<b>Crystal-EEG Model 10</b>	<b>Hambrecht Associates Multi-Channel Electroencephalographic Telemetry System</b>
<b>1) Transmitter and Receiver Assembly</b>	8 channel Dynamic range of inputs is +/-300 $\mu$ V Radiofrequency 902-928 MHz Operating Range 10-20 feet	4 channels Dynamic range of inputs is 5-250 $\mu$ V Radiofrequency 88-108 MHz Operating Range 200 feet
<b>2) Software</b>	three modules	None
<b>3) PC Operator Interface</b>	Optional	None

**K) Bench Testing:** The noise amplitude of the various channels of three Crystal-EEG Model 10 Transmitters was evaluated by shorting the input channels of the transmitter units together. The transmitted signal (noise) at the receiver end was recorded. **Figure 1** shows the results for the 24 channels of transmitted data (8 channels/Transmitter). The RMS of the noise was in the order of 1 uVolt.

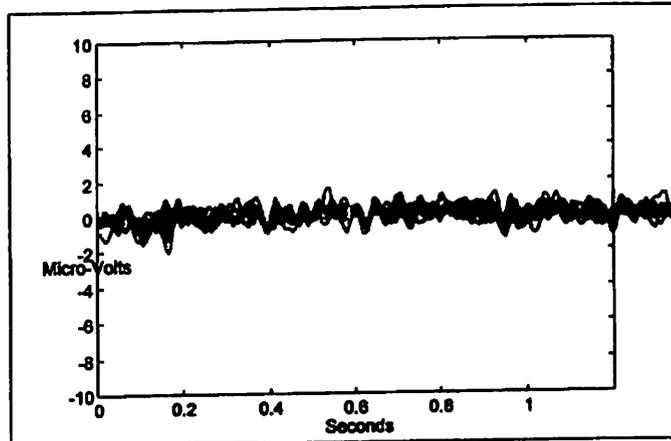


Figure 1. Noise when 24 channels shorted

The Crystal-EEG Model 10 unit was then evaluated in its ability to measure and transmit known analog waveforms. The analog signals were provided by a signal generator. Figures 2 and 3 show two examples of such data from one typical channel with the analog sine waves at 5 and 20 Hz, respectively. For both cases the sine waves were measured and transmitted across the link.

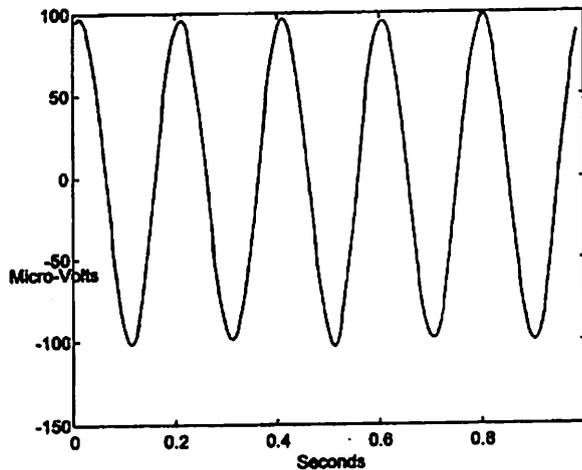
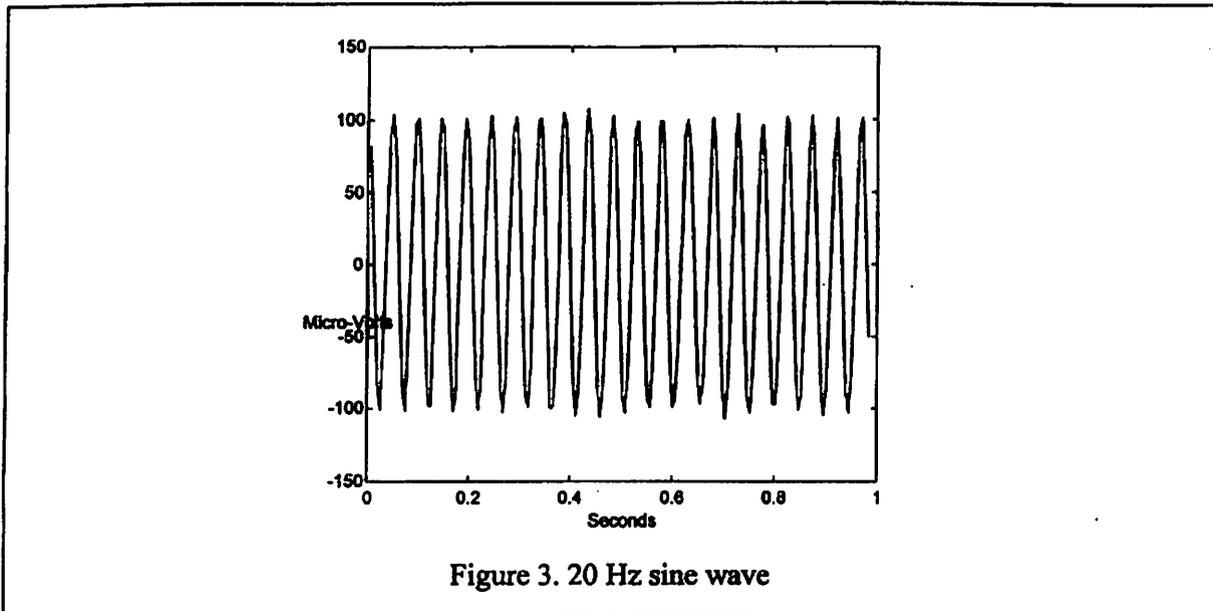


Figure 2. 5 Hz Sine Wave



The next step was to verify the functional accuracy of the low and high pass filters. The frequency of a sine wave was varied between 0.12 and 80 Hz and the peak values of the sine waves recorded. Table 1 shows the measured peak value for each frequency. These data verify the accuracy of the implemented filters by showing expected levels of attenuation at the both ends of the spectrum.

**Table 1. Frequency Response of the System to 100 uV Amplitude Sine Waves**

Sine Wave Frequency (Hz.)	Peak Amplitude (uV)
0.12	12
0.2	22
0.4	45
0.7	69
1.0	83
2.0	95
5.0	97
10	98
20	100
30	72
40	18
50	6
60	5
80	3



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

Mr. Robert N. Schmidt  
Cleveland Medical Devices, Inc.  
11000 Cedar Avenue, Suite 439  
Cleveland, Ohio 44106

Re: K970672

Trade/Device Name: Crystal -EEG™ Model 10

Regulation Number: 21 CFR 882.1400

Regulation Name: Electroencephalograph

Regulatory Class: II

Product Code: OMC

Dated (Date on orig SE ltr): February 19, 1997

Received (Date on orig SE ltr): February 24, 1997

APR - 9 2012

Dear Mr. Schmidt:

This letter corrects our substantially equivalent letter of May 22, 1997.

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):** K970672

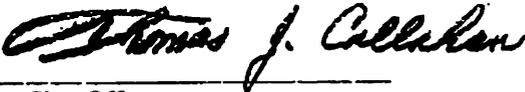
**Device Name:** Crystal-EEG™ Model 10

**Indications For Use:** ..... The Crystal-EEG Model 10 is a mobile, intermediate range, ..... wireless EEG system intended to be used for measuring and transmitting electroencephalogram (EEG) signals.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K970672

**Prescription Use**    X  
(Per 21 CFR 801.109)

OR

**Over-The-Counter Use**