



One Bio-logic Plaza Mundelein, Illinois 60060-3700 1-800-323-8326 Fax: 847-949-8615

K973883

MAR - 5 1998

SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning this Modification to Ceegraph for 128-Channel Recording is summarized below.

Because this is not a CLASS III device, the special certification defined for this section is not required.

PREPARED BY: Bio-logic Systems Corp
One Bio-logic Plaza
Mundelein, IL 60060

TELEPHONE: (847)-949-5200

CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: October 13, 1997

NAME OF DEVICE: Bio-logic CEEGRAPH 128-Channel Recording System.

COMMON NAME: Digital EEG Recorder.

CLASSIFICATION NAME: Electroencephalograph (per CFR 882.1400).

PREDICATE DEVICE: Bio-logic Ceegraph Digital EEG System , 510(k) #K933233.

DESCRIPTION OF THE DEVICE:

The 128-Channel data collection system consists of a metal enclosure approximately 13.5" x 7.375" x 5.25" in size, weighing approximately 10.9 lb (when fully-equipped to handle all 128 channels). It can be configured to perform from 16 to 128 channel collection, depending on the hardware installed in the box. Power to the box is supplied with an external medical-grade power supply, which supplies regulated 12 volts and 5 volts DC to a connector at the rear of the box. Communication to the host computer is performed through a standard Ethernet interface connector capable of running at data rates up to 10 MHz (10 base-T). Four patient connectors are provided on the front of the box, each capable of interfacing to 32 channels of patient input. A sync connector is provided at the rear of the box, to provide synchronization and sampling rate information to external devices.

The system consists of a microprocessor board, a digital interface board, and up to eight (8) 16-channel analog boards connected to the system through a backplane interconnect board. The analog boards are identical to the 16-channel analog boards used in the patient connection module (headbox) of the predicate device. These boards provide patient isolation and signal amplification. Boards are connected in pairs to one of the four external connectors on the front of the unit. These 50-pin external connectors are identical to the auxiliary connector on the present headbox of the predicate device. This allows the use of existing patient connection hardware, such as electrode arrays and the 32-channel" electrode connection panel called the "quick disconnect box". The microprocessor board contains program and data memory and control functions for reading the analog data, converting it to digital, and communicating it to the host computer through the Ethernet cable. The digital interface board contains the interface to the A/D converters and the communications hardware.

INTENDED USE:

The Bio-logic Ceegraph family is intended for use in the recording and analysis of routine EEG tests. Typical EEG tests are 20-30 minutes in duration, but the Ceegraph system can also be used for longer tests, including continuous long-term EEG monitoring with patient video. EEG testing is intended for use whenever it is necessary to measure and record the electrical activity of a patient's brain by attaching multiple electrodes at various locations on the scalp. The 128 Channel Data Recording system has a similar intended use to that of the 32 channel Ceegraph recording system (predicate device). It can be used for patients of all ages, from newborn infants through adults, to and including geriatric patients.

PATIENT POPULATION: Adults, children and infants.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The 128-Channel Data Recording System uses substantially the same technical design approach as that of the predicate device patient connection module (headbox). The predicate device employs a microprocessor-based digital control board, a patient interface board, and two 16-channel analog boards. The same analog boards are used in the 128-Channel system, which can accommodate up to eight of them. The digital board is an updated design incorporating a more powerful microprocessor and more memory, and the digital control, interfacing and communications functions are contained on two boards instead of one, as in the predicate device. The method of communication to the host computer is through high-speed Ethernet cable, whereas the predicate device uses an RS-422 serial communication interface.

Both the predicate device and the 128-Channel System require only low-voltage DC power for operation. Patient isolation is provided through the use of optical isolators on the interface board. In addition, the 128-Channel System connects to the host computer through a transformer-coupled Ethernet connector, which provides a second level of isolation.

SUMMARY OF NON-CLINICAL TESTING:

The following is a list of tests performed on the 128-Channel Data Recording System to demonstrate that the performance of the system is equivalent to that of the predicate device in terms of safety and effectiveness, and that the additional features provide utility and product performance which exceeds that of the predicate device. All tests were completed satisfactorily with no adverse reports.

1. EMI/EMC Testing per FDA Reviewer's Guidance (November, 1993):
 - a.) CISPR 11 Conducted and CISPR 11 A Radiated Emissions
 - b.) ENV 50140 Radiated Susceptibility Test
 - c.) EN 61000-4-4 Transient Susceptibility Test
 - d.) EN 61000-4-5 Surge Susceptibility Test
 - e.) EN 61000-4-6 and CS114 Conducted Immunity Tests
 - f.) RE101 Magnetic Emissions Test
 - g.) RS101 and 60 Hz Magnetic Susceptibility Tests
 - h.) EN 61000-4-8 Voltage Fluctuations Test
 - i.) Reviewer's Guide Quasi-static Fields Test
 - j.) Military Standard 461C CS02 Test
 - k.) EN 60555-2 Power Line Harmonics Test Prescan
2. Current Leakage Tests per ANSI/AAMI, *Safe Current Limits for Electromedical Apparatus*.
3. Dielectric Withstand Test per FDA Reviewer's Guidance and IEC 601-1.
4. Power Line Variations per FDA Reviewer's Guidance.
5. Power Line Transients per FDA Reviewer's Guidance.
6. Temperature testing per FDA Reviewer's Guidance.
7. Electrostatic Discharge Tests (ESD) per FDA Reviewer's Guidance and EN60601-2.
8. Data Integrity Tests to demonstrate that digital data collected is a correct representation of the analog signals that are applied at the patient inputs.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1998

Mr. Norman E. Brunner
Vice-President of R&D
Bio-logic Systems Corporation
One Bio-logic Plaza
Mundelein, Illinois 60060-3700

Re: K973883
Trade Name: Bio-logic Ceegraph 128-Channel Recording
System
Regulatory Class: II
Product Code: GWQ
Dated: January 26, 1998
Received: January 27, 1998

Dear Mr. Brunner:

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.

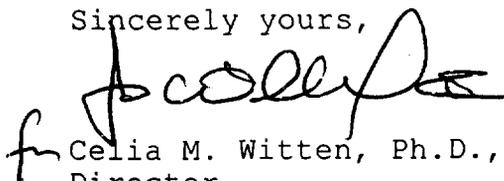
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Brunner

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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

