K021215

MAY 1 5 2002

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SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

Safety and effectiveness information concerning the ABaer Cub device modification to the Bio-logic Evoked Potential product family 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
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CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: April 12, 2002

NAME OF DEVICE: Bio-logic ABaer Cub.

COMMON NAME: Evoked Response System.

CLASSIFICATION NAME: Evoked Response Auditory Stimulator (per CFR 882-1900).

PREDICATE DEVICE: ABAER / Navigator Pro Evoked Potential device, reference 510(k) #K994149.

DESCRIPTION OF THE DEVICE:

The Bio-logic Evoked Potential family of products is intended to be used for the recording and analysis of human physiological data for the purpose of neurological diagnosis and treatment of sensory disorders. The predicate device referenced above is the latest in a series of systems of this type marketed by Bio-logic. Other related devices comprising the Evoked Potential family include:

1. 510(k) #K803226 – Bio-logic Evoked Response Stimulators.
2. 510(k) #K842543 – Bio-logic Evoked Potential System.
3. 510(k) #K844992 – Bio-logic Portable Evoked Response System.
4. 510(k) #K862690 – Bio-logic Traveler LT System.
5. 510(k) #K930328 – Navigator and Traveler Evoked Potential Product.

The ABaer Predicate Device performs Evoked Potential screening, recording and analysis functions, provides one channel of data recording, and includes the Point Optimized Variance Ratio (POVR) algorithm for optimizing signal quality, implementing the screening function and enhancing speed of test completion. This new ABaer Cub device performs these same functions in essentially the same ways, but has hardware and software modifications and improvements over the Predicate device, primarily to enhance portability and ease of use.

The Predicate Device describes the use of the POVR algorithm to monitor the signal-to-noise ratio of the averaged response signal every 256 stimulation-response cycles. This modified device, ABaer Cub, incorporates the same POVR algorithm for the same purpose, to yield high-quality test results in the shortest possible time. In addition, the feature modifications for this new device include the use of a Personal Digital Assistant (PDA) or "Pocket PC" which can be hand-carried separately or mounted right on the ABaer box, resulting in a completely battery-powered, portable hand-held test instrument. The Predicate Device uses a desktop or laptop computer instead of the PDA. The electronic hardware is very similar in design to the ABaer hardware used in the Predicate Device. The enclosure has been made slightly larger (deeper) to allow space to incorporate a rechargeable battery inside the unit. New circuitry for charging the battery has also been added to the unit, and the small LCD display in the ABaer has been removed from the ABaer Cub. The functions of the hardware are substantially the same as those of the Predicate Device hardware. The ABaer predicate device communicates test information and results to a separate host computer (desktop PC or laptop) through a serial communications port. In the ABaer Cub, this host computer is now a PDA or "pocket PC" (for instance, the Hewlett-Packard Jornada) which can be affixed right on the ABaer unit or hand-carried separately. Because both the PDA and the ABaer unit are battery powered, this significantly improves the portability and usability of the device. The ABaer Cub software for control of this device is a simplified subset of the ABaer Predicate Device software, with some GUI changes necessary to enhance the graphics display for use with the smaller PDA LCD screen. The host software for the Predicate Device is Windows 95/98/ME based, whereas the host software for the ABaer Cub is Windows CE based. The C++ programming language is used in both cases. Together, these minor hardware and software changes implement the same functionality and perform the same intended use as the Predicate Device, but with improved portability and ease-of-use.

INTENDED USE:

The Bio-logic Evoked Potential (EP) product family is indicated for use in the recording and analysis of human physiological data necessary for the diagnosis of auditory and hearing-related disorders.

This product, the ABaer Cub, like it's predicate device, the ABaer, is especially indicated for use in the screening of infants to determine hearing loss.

The Bio-logic EP System can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults. The use of the Bio-logic EP family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

SAFETY AND EFFECTIVENESS SUMMARY

To establish the safety and effectiveness of this modification to the Bio-logic Evoked Potential software, the modification was designed and incorporated into the product in accordance with the Bio-logic internal Product Development procedures which are intended to meet ISO-9001, EN-46001 and FDA QSR Design Control specifications. A detailed Hazard/Risk analysis for the EP family of products was performed using the Fault Tree analysis (FTA) approach, and a detailed Risk Assessment was written in accordance with EN-1441, the International Standard for Hazard/Risk analysis. An addendum to this Hazard/Risk file was written based on a review of this new ABaer Cub design.

The ABaer Cub patient-connection hardware is basically the same as that of the ABaer. There are no newly-introduced hardware-related methods by which the patient can be harmed or injured through the use of this device. The same patient isolation methods are used in both products. Both devices utilize a medical-grade power supply, although the ABaer Cub will be used most often in its portable, battery-operated mode. Direct hardware control of all ABaer Cub functions is provided from the Digital Signal Processor (DSP) and its program code located inside the ABaer Cub package, just as it is in the ABaer. By distributing the hardware-specific functions to the DSP, the Windows-based host computer program has fewer real-time demands, resulting is high reliability and performance.

Nurses, audiologists, and physicians can use the ABaer Cub system. No knowledge of or training in Evoked Potentials is necessary. Anyone, even a user with limited computer skills, who has been trained to operate this equipment and trained in techniques for proper infant handling, can use the ABaer Cub effectively.

The ABAER Cub software does not make any final decisions that result in any direct forms of diagnosis or treatment. The Pass/Refer recommendations of the automated screening process in the ABaer Cub can be reviewed, if desired, by a qualified health care professional, and may be modified, overridden or deleted as determined by the qualified user. The program provides additional functionality to allow the qualified user to review all raw data collected, and to perform other data analysis to suit his or her requirements. This optional data review capability allows the Physician to view the same data that the ABaer Cub used to make its recommendations.

The chart on the following page provides a summary comparison of the technological characteristics of the new ABaer Cub device relative to the predicate ABaer device. This is to demonstrate that this new ABAER Cub device has no significant differences which would adversely affect product safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2002

Mr. Norman E. Brunner
Vice-President of Research and Development
Bio-logic Systems Corporation
One Bio-logic Plaza
Mundelein, IL 60060-3700

Re: K021215
Trade/Device Name: Bio-logic Abaer Cub
Regulation Number: 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ
Dated: April 16, 2002
Received: April 17, 2002

Dear Mr. Brunner:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

INDICATIONS FOR USE STATEMENT.

510(k) Number (if known): **Not Assigned** K021215

Device Name: **ABaer Cub, Modification to Bio-logic Evoked Potential Product.**

Indications For Use:

The Bio-logic Evoked Potential (EP) product family is indicated for use in the recording and analysis of human physiological data necessary for the diagnosis of auditory and hearing-related disorders.

This product, the ABaer Cub, like it's predicate device, the ABaer, is especially indicated for use in the screening of infants to determine hearing loss.

The Bio-logic EP System can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults. The use of the Bio-logic EP family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

(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 K021215

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

(Optional Format 1-2-96)