K021801

JUN 27 2002

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SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

Safety and effectiveness information concerning the ABaer Cub with OAE device modification to the Bio-logic Hearing Screening 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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Mundelein, IL 60060

TELEPHONE: (847)-949-5200

CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: May 24, 2002

NAME OF DEVICE: Bio-logic ABaer Cub with integrated OAE and ABR functions.

COMMON NAME: Audiometer (OAE) and Evoked Response (ABR).

CLASSIFICATION NAME: Audiometer (reference 21CFR 874.1050) and Auditory Evoked Response system (reference 21CFR 882.1900).

PREDICATE DEVICE: The OAE function is substantially equivalent to the Sport/AuDX predicate device (510(k) #K974076) and the ABR function is substantially equivalent to the ABaer Cub predicate device (510(k) #K021215).

DESCRIPTION OF THE DEVICE:

The Bio-logic Hearing Screening products, including the OAE and ABR test instruments Scout/AuDX and ABaer Cub, are intended to be used for the purpose of testing for hearing loss in patients of all ages, but primarily in infants . The predicate devices referenced above are the latest current products of this type marketed by Bio-logic. This new product, ABaer Cub with OAE, is the integration of both OAE and ABR screening functions into one portable unit, the ABaer Cub, with additional OAE software functions added to the Pocket PC host computer for the ABaer Cub.

The ABaer Cub 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 with OAE device performs these same functions in the same ways, but has the added capability of performing the OAE tests of the Sport/AuDX predicate device, all within the same hardware package as the ABaer Cub.

The Sport/AuDX predicate device can be used in either a stand-alone (AuDX) or host-connected (Sport) mode. The same DSP software is used in both types of box. The primary difference between the two products is that the Sport requires the use of a host computer for user control information and to store and display the data returned from the Sport box. For the AuDX, all user control and display is right at the AuDX box, making this a fully portable test instrument but with limited control and display capability. However, after an AuDX test is completed, it can be connected to a host computer to download test data for display on the host computer screen if desired. This same Sport/AuDX DSP software functionality has been incorporated into the ABaer Cub box. Much of the Sport host computer display software has been incorporated into the ABaer Cub Pocket PC (host computer), resulting in a completely battery-powered, portable hand-held test instrument capable of performing both the Automated OAE and ABR tests. The Sport OAE predicate device uses a desktop or laptop computer instead of the Pocket PC. The electronic hardware is the same as the ABaer Cub hardware used in that predicate device. Because both the Pocket PC and the ABaer Cub unit are battery powered, this significantly improves the portability and usability of the device over that of the Sport OAE predicate device. The ABaer Cub software for control of this device is a combination of the Sport and ABaer Cub predicate device software, with some GUI changes necessary in the Sport OAE software to modify the graphics display for use with the smaller Pocket PC LCD screen. The host software for the Sport/AuDX OAE predicate device is written in the C++ programming language for the Windows 95/98/ME operating system, whereas the host software for the ABaer Cub is written in the C++ programming language for the Windows Pocket PC operating system. Together, these software additions implement the same functionality and perform the same intended use as both predicate devices, but with improved portability and ease-of-use.

INTENDED USE:

The Bio-logic Otoacoustic Emissions (OAE) and Evoked Potential (EP) product families are 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 with Automated OAE and ABR, like it's predicate devices, the AuDX and the ABaer Cub, is especially indicated for use in the screening of infants to determine hearing loss.

The Bio-logic OAE and EP Systems 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 OAE and EP families of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2002

Bio-logic Systems Corp.
c/o Norman E. Brunner
Vice-President of Research & Development
One Bio-logic Plaza
Mundelein, IL 60060-3700

Re: K021801
Trade/Device Name: ABaer Cub with Automated OAE and ABR
Regulation Number: 21 CFR 874.1050 & 21 CFR 882.1900
Regulation Name: Audiometer & Auditory Evoked Response System
Regulatory Class: Class II
Product Code: EWO & GWJ
Dated: May 31, 2002
Received: June 3, 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) 594-4613. 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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Device Name: ABaer Cub with Automated OAE and ABR.

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joma K. Kana Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K021801

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

(Optional Format 1-2-96)