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K012384

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SECTION 10
BIO-LOGIC EAR MUFFINS ® 510(k)

PREMARKET NOTIFICATION 510(k) SUMMARY

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

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CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: July 20, 2001

NAME OF DEVICE: Bio-logic Ear Muffins®

COMMON NAME: Earphones for Evoked Response auditory stimulus delivery.

CLASSIFICATION NAME: Accessory to primary device, classification: Stimulator, Auditory, Evoked Response, (per 21 CFR section 882.1900).

PREDICATE DEVICE: Natus Medical Inc. Ear Coupler Earphones, part of ALGO Disposable Kit used with ALGO-2 Newborn Hearing Screener, 510(k) #K936039.

DESCRIPTION OF THE DEVICE:

The Bio-logic Ear Muffins consist of a pair of single-use, disposable foam & plastic donut-shaped devices for delivering sound to the human ear. The Ear Muffin is specifically designed in size and shape to be used with infants. The Ear Muffin is one of the alternative sound delivery devices offered as accessory options to the ABaer and Navigator Pro product lines. The ABaer/Navigator Pro has received FDA Marketing Clearance via 510(k) #K994149. The Ear Muffins can also be used as a stand-alone device with the Natus Medical ALGO series of Newborn Hearing Screening systems, as demonstrated in the test results within this 510(k) notification.

Electrical safety is not an issue with the Ear Muffins, because the Ear Muffin is not electrical in nature, it is simply a different tubing system for sound delivery to the ear. The Ear Muffins connect to the output of Auditory Stimulator device (e.g., Natus ALGO), and provide an acoustic pathway to direct the auditory stimulus to the ear of the infant. The Muffins are applied to the baby's head to cover the ears, similar to the way a large set of headphones might cover the ears of an adult.

The Ear Muffin only makes very brief contact with the skin, and does not contact in vivo body tissues or fluids. The material used for the Ear Muffins has been found to be safe for this use by its manufacturer through appropriate biocompatibility testing.

INTENDED USE OF THE DEVICE:

The Bio-logic Ear Muffins® is a disposable earphone device intended to be used as an accessory to the Bio-logic ABaer / Navigator Pro auditory evoked response screening and diagnostic systems, and the Natus Medical Inc. ALGO series auditory evoked response screening systems. The Ear Muffins® device performs as the means for delivering the auditory stimulus from the auditory stimulator to the ear of the patient under test.

The Bio-logic Ear Muffins® device is especially indicated for use in the auditory evoked response screening of newborn infants, because the Ear Muffins® can be placed to cover the entire ear of the infant, so nothing has to be placed into the ear canal.

COMPARISON SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

PARAMETER FOR COMPARISON	Bio-logic Systems Corp. Ear Muffins®	Similarity or difference to Predicate Device
Indications for Use	Auditory Evoked Response screening for infants.	Same.
Target Population	Newborn & very young infants.	Same.
Design	Lightweight foam & plastic donut-shape covered earphones with plastic tubing connecting to stimulator	Slight differences in size, shape and thickness of materials.
Materials	Disposable foam & plastic.	Very similar.
Performance	Average stimulus strength measured in ear canal is 79.28 dB SPL with standard deviation of 1.34 dB SPL.	Same to within less than 1 dB SPL.
Sterility	Not supplied sterile.	Same.
Biocompatibility	All materials successfully passed biocompatibility testing.	Same.
Mechanical Safety	No mechanical parts.	Same.
Chemical Safety	No chemicals involved in the use of this device.	Same.
Anatomical Sites	Device is placed covering the ear of newborn infants.	Same.
Human Factors	Simple, easy-to-follow instructions are provided.	Same.
Energy Used and/or Delivered	Device is passive and consumes no energy. Only Auditory energy is delivered as noted above.	Same.
Standards Met	Associated with stimulation device.	Same.
Electrical Safety	Device not electrical in nature.	Same.
Thermal Safety	Device not thermal in nature.	Same

DISCUSSION AND ASSESSMENT OF NON-CLINICAL PERFORMANCE DATA:

Non-clinical testing was performed to demonstrate the substantial equivalence of the Bio-logic Ear Muffins® to the Natus Medical Inc. Ear Couplers. This performance testing consisted of measuring the sound level within the ear canal of a large number of test subjects, using the Natus ALGO-2 device with (1) the Natus Ear Coupler and (2) the Bio-logic Ear Muffins®. The average of all sound levels measured with (1) was within 1 dB SPL of the average of all sound levels measured with (2). Standard deviation for the results of tests (1) and (2) were approximately 1.4 dB SPL in both cases. Therefore, it is concluded that the performance of the Bio-logic Ear Muffins® is very similar to that of the Natus Medical Inc. Ear Coupler, and it is therefore substantially equivalent to this predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 5 2001

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

Re: K012384
Trade/Device Name: Bio-logic Ear Muffins
Regulation Number: 882.5050
Regulation Name: Biofeedback device
Regulatory Class: II
Product Code: HCC
Dated: July 26, 2001
Received: July 27, 2001

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,

Susan Walker, MD

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** K012384

Device Name: Bio-logic Ear Muffins®

Indications For Use:

The **Bio-logic Ear Muffins®** is a disposable earphone device intended to be used as an accessory to the Bio-logic ABaer / Navigator Pro auditory evoked response screening and diagnostic systems, and the Natus Medical Inc. ALGO series auditory evoked response screening systems. The **Ear Muffins®** device performs as the means for delivering the auditory stimulus from the auditory stimulator to the ear of the patient under test.

The **Bio-logic Ear Muffins®** device is especially indicated for use in the auditory evoked response screening of newborn infants, because the **Ear Muffins®** can be placed to cover the entire ear of the infant, so nothing has to be placed into the ear canal.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K012384

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

(Optional Format 1-2-96)