JUL 16 2003

K031352

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Section 10:

Premarket Notification 510(k) Summary

Date of which the Summary was Prepared: April 25, 2003

Submitted By: Bio-logic Systems Corp.
One Bio-logic Plaza
Mundelein, IL 60060

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Contact Person: Erik Gundersen

Name of Device: Bio-logic Insert Earphones

Common Name: Earphones for Evoked Response auditory stimulus delivery

Classification Name: Accessories to devices with classification:
Stimulator, Auditory, Evoked Response,
(per 21 CFR section 882.1900)

Predicate Device: Etymotic Research ER-3 Insert Earphones, 510(k)
#K930003

510(k) NOTIFICATION FOR BIO-LOGIC INSERT EARPHONES

Description of the Device:

The Bio-logic Insert Earphones are transducers that convert electrical stimulus, provided by the Bio-logic ABaer / Navigator Pro Auditory Evoked Response Stimulators, into acoustic stimulus, which is then coupled to the patient's ears. They are comprised of five sections: 1.) Electrical Transmission Path, 2.) Electrical Filter, 3.) Speaker, 4.) Acoustic Transmission Path, and 5.) Transducer Case.

The Electrical Transmission Path consists of a shielded cable. The cable is connected to the Bio-logic ABaer / Navigator Pro Auditory Evoked Response Stimulators, by means of a 6-pin Mini DIN. The other end of the cable is connected to the left and right Electrical Filter Sections.

Each Electrical Filter section (left and right) consists of a passive analog filter to provide electrical pre-emphasis response shaping to the stimulus prior to reaching the Speakers.

Each Speaker (left and right) converts the electrical stimulus into an acoustic stimulus. The acoustic stimulus is delivered to the patient's ear by means of the Acoustic Transmission Path.

Each Acoustic Transmission Path (left and right) consists of silicon tubing and a tube nipple. The tube nipple provides acoustic and mechanical connection to a disposable eartip. The disposable eartips interface to the patient's ear and deliver the acoustic stimulus.

Each Transducer Case (left and right) houses an Electrical Filter and Speaker and provides means of handling and labeling.

Intended Use of the Device:

The Bio-logic Insert Earphones are accessories to the Bio-logic ABaer / Navigator Pro Auditory Evoked Response systems. The Bio-logic Insert Earphones devices perform as the means for delivering auditory stimulus to the ears of the patient under test. The interface to the ears of the patient is provided by means of disposable foam eartips, designed to fit infants, children, and adults.

Comparison Summary of Technological Characteristics:

Parameter for Comparison	Etymotic Research ER-3 Insert Earphones (510(k) #K930003)	Bio-logic Insert Earphone	Bio-logic Broadband Insert Earphone
Intended Use	Auditory Evoked Response	Same	Same
Target Population	Infants, Children, and Adults	Same	Same
Human Factors	Simple, easy-to-follow instructions are provided.	Same	Same
Design	Transducer and circuit mounted in a case. Connected to the test device via a cable, and connected to the patient via silicon sound tube and foam eartip.	Similar physical design with different cable type and slightly different acoustics.	Similar physical design with different cable type, transducer type, acoustics and filter to produce a broader band frequency response at a lower output.
1 kHz Sensitivity (re IEC 711 Coupler @ 1.0 Vrms AC Drive)	114 dB SPL	111 dB SPL	85 dB SPL
Frequency Bandwidth (± 5 dB)(re IEC 711 Coupler)	100 Hz – 4,000 Hz	Same	100 Hz – 10,000 Hz
Energy Used and or Delivered	Device is passive and consumes less than 0.5 Wpeak. This electrical energy is converted into acoustic energy and delivered to the patient's ear.	Same	Same
Standards Met	Associated with stimulation device	Same	Same
Bio-compatibility	All material passed bio-compatibity testing	Same	Same
Sterility	Not supplied sterile	Same	Same

Parameter for Comparison	Etymotic Research ER-3 Insert Earphones (510(k) #K930003)	Bio-logic Insert Earphone	Bio-logic Broadband Insert Earphone
Compatibility with Environment	No environmental issues	Same	Same
Chemical Safety	No chemicals involved in the use of this device.	Same	Same
Thermal Safety	Device does not contain any thermal producing components.	Same	Same
Mechanical Safety	Device does not contain any moving components.	Same	Same
Electrical Safety	Patient is isolated from device via silicon sound tube and foam eartip.	Same	Same

Discussion and Assessment of Non-Clinical Performance Data:

Non-clinical testing was performed to demonstrate the substantial equivalence of the Bio-logic Insert Earphones to the Etymotic Research ER-3 Insert Earphones. This performance testing consisted of measuring the sound level within a Bruel & Kjaer Type 711 Occluded Ear simulator using a Bio-logic Navigator Pro Auditory Evoked Response Stimulator with the Etymotic Research ER-3 Insert Earphone, the Bio-logic Insert Earphone, and the Bio-logic Broadband Insert Earphone.

The test results show that the sound level output of the Bio-logic Insert Earphone is an average of 3 dB lower than the Etymotic ER-3 Insert Earphone. This difference in output is calibrated by increasing the drive signal by +3 dB. After the calibration, the resulting frequency response is nearly

The test results show that the sound level output of the Bio-logic Broadband Insert Earphone is an average of 29 dB lower than the Etymotic ER-3 Insert Earphone. This difference is due to the fact that Bio-logic Broadband Insert Earphone was designed to have a much smoother, wider bandwidth frequency response. The Bio-logic Broadband Insert Earphones are a special version of the Bio-logic Insert Earphones and are utilized **ONLY** for applications where wider bandwidth is required.

Therefore, it is concluded that the performance of the Bio-logic Insert Earphones is very similar to that of the Etymotic ER-3 Insert Earphone (510(k) #K930003), and they are 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

JUL 16 2003

Bio-Logic Systems Corporation
c/o Erik C. Gundersen
Design Engineer IV
One Bio-logic Plaza
Mundelein, IL 60060

Re: K031352
Trade/Device Name: Bio-logic Insert Earphones
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: April 25, 2003
Received: April 30, 2003

Dear Mr. Gundersen:

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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Section 8:

Statement for Indications for Use

510(k) Number (if known): K031352

Device Name: **Bio-logic Insert Earphones**

Indication For Use:

The **Bio-logic Insert Earphones** are accessories to the Bio-logic ABaer / Navigator Pro Auditory Evoked Response systems. The **Bio-logic Insert Earphones** devices perform as the means for delivering auditory stimulus to the ears of the patient under test. The interface to the ears of the patient is provided by means of disposable foam eartips, designed to fit infants, children, and adults.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

(Optional Format 1-2-96)

Prescription Use ✓ GMC
(Per 21 CFR 801.109)

510(k) Number K031352