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JUL 1 2002

K021895

SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

Safety and effectiveness information concerning the MASTER 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
One Bio-logic Plaza
Mundelein, IL 60060

TELEPHONE: (847)-949-5200

CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: June 4, 2002

NAME OF DEVICE: Bio-logic MASTER Evoked Response System.

COMMON NAME: Evoked Response System.

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

PREDICATE DEVICE: 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 diagnostic systems of this type marketed by Bio-logic. Other related diagnostic devices in 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 predicate device, the Bio-logic Evoked Potential system with Navigator Pro hardware, performs Evoked Potential recording and analysis functions, including up to 2 channels of data recording and numerous diagnostic protocols and modalities. This new MASTER Evoked Potential with Navigator Pro device performs many of these same functions in essentially the same ways with a one-channel version of the same hardware, but employs a new software application package with significant new capabilities over those of the predicate device. Through the use of the Auditory Steady State Response (ASSR) modality, which is a variant of the MLR / 40 Hz test modality used in the referenced systems already on the market, hearing threshold levels can quickly and reliably be determined based on physiological rather than behavioral means.

The Auditory Steady State Response test is an alternative to tone burst Auditory Brainstem Response (ABR) testing which is used to predict frequency-specific behavioral hearing thresholds particularly for patients who cannot provide a reliable behavioral response. The ASSR technique avoids one of the inherent pitfalls of the tone burst ABR technique which is the problem of "spectral splatter" (distortions in frequency-specific data due to the start/stop actions of the tone burst) of the short duration acoustic stimulus that is required for ABR measurement. The ASSR technique uses a continuous frequency and/or amplitude modulated tone as the stimulus and can combine several stimuli together simultaneously to assess responses to various frequencies all at the same time. The evoked response recorded from scalp electrodes is reflective of the frequency of the modulation envelope of the stimulus. Thus, assessment of the response spectrum can yield information about the presence or absence of the response to stimuli of varying intensities in order to determine the response threshold. ASSR thresholds have a predictable relationship to behavioral thresholds that is dependent on stimulus frequency and the presence and degree of hearing loss.

The MASTER application software is a modification of software originally designed by and exclusively licensed from researchers at the Rotman Research Institute, Baycrest Centre for Geriatric Care, at The University of Toronto. This software was designed originally for research purposes, and Bio-logic made significant modifications to create double fault conditions for any situation that could impact patient safety (e.g. presentation of prolonged, intense acoustic stimuli), to block the user from making parameter changes that are known to result in poor quality data, and to improve overall reliability, performance and ease of use. Additionally, the user interface has been simplified in terms of operation and information display so that only the relevant operations and data are available. More complex functions that do not have clinical relevance were eliminated from the software.

This system will be used to assist in defining the configuration of the hearing loss particularly in populations that are difficult to test using traditional behavioral audiometry. It is designed to be used as a diagnostic test procedure by individuals who are trained in the performance and interpretation of evoked potentials such as audiologists and physicians. The results of the test will be used by trained hearing health care professionals to make recommendations regarding appropriate intervention strategies.

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, MASTER, like its predicate device, the Navigator Pro, is a diagnostic device intended to be used as part of a set of audiometric test protocols. It is especially indicated for use in defining the configuration of the hearing loss particularly for individuals whose behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults. It allows for the estimation of behavioral hearing threshold at various frequencies, through the use of ABR (Auditory Brainstem Response) or ASSR (Auditory Steady-State Response) test protocols. It is designed to be used as a diagnostic test procedure by individuals who are trained in the performance and interpretation of evoked potentials such as audiologists and physicians. The results of the test will be used by trained hearing health care professionals to make recommendations regarding appropriate intervention strategies.

Bio-logic EP Systems can be used for patients of all ages, from children to adults, including infants and geriatric patients. 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 MASTER software design.

The Navigator Pro patient-connection hardware is unchanged with this modification. A one-channel version of this hardware is used with the MASTER program. 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, and the Navigator Pro utilizes a medical-grade power supply. Direct hardware control of all Navigator Pro functions is provided from the Digital Signal Processor (DSP) and its program code located inside the Navigator Pro package, just as it is in the predicate device. 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.

The MASTER software does not make any final decisions that result in any direct forms of diagnosis or treatment. The system is designed to be used for auditory diagnostic testing by trained health care professionals. Audiologists and physicians perform evoked potential testing and interpret the results. The results of the test are then used by trained hearing health care professionals to make recommendations regarding appropriate intervention strategies.

The following table provides a summary comparison of the technological characteristics of the new MASTER device relative to the Bio-logic Evoked Potential with Navigator Pro predicate device. This is to demonstrate that this new MASTER device has no significant differences which would adversely affect product safety and effectiveness.

Parameter for Comparison	**Similarity or Difference**
Intended Use	No differences.
Patient Population	No differences.
Hardware Configuration	No differences.
Computer Control Software	The software for the MASTER is a new Windows-based program designed specifically for the collection of Auditory Steady State Response (ASSR) data. The predicate device was DOS-based and performed a variety of ABR tests, including the 40 Hz test of which ASSR is a variant.
Navigator Pro Firmware	The Digital Signal Processor (DSP) code in the Navigator Pro hardware box utilizes the same Loader program as in the predicate device. The program downloaded from the host computer has changes in order to perform the AM/FM modulated stimulation signals for ASSR testing.
Patient information and tracking	No significant differences.
Safety Characteristics	No differences. The basic patient connection methods and isolation circuits are the same for both products.
Product Labeling	Labeling on the Navigator Pro is unchanged.
Presentation of Data / User Interface	Information displayed on the host computer screen has been completely changed in the MASTER. The user interface is specifically designed to allow the user to enter test protocol information and display results in a manner more intuitive and familiar to Windows users, as opposed to the DOS user interface of the predicate device. Also, the overall display of data is less complex than that of the predicate device.
Patient connections (transducers and electrodes)	No differences
Anatomical sites	No differences.
Physical Characteristics	No differences.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

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

Re: K021895
Trade Name: Bio-logic Master Evoked Response System
Regulation Number: 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: II
Product Code: GWJ
Dated: June 7, 2002
Received: June 10, 2002

Dear Mr. Brunner:

We have reviewed your Section 510(k) premarket 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) 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) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

510(k) Number (if known): #K021895

Device Name: MASTER, 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, MASTER, like its predicate device, the Navigator Pro, is a diagnostic device intended to be used as part of a set of audiometric test protocols. 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. It allows for the estimation of behavioral hearing threshold at various frequencies, through the use of ABR (Auditory Brainstem Response) or ASSR (Auditory Steady-State Response) test protocols. It is designed to be used as a diagnostic test procedure by individuals who are trained in the performance and interpretation of evoked potentials such as audiologists an physicians. The results of the test will be used by trained hearing health care professionals to make recommendations regarding appropriate intervention strategies.

Bio-logic EP Systems can be used for patients of all ages, from children to adults, including infants and geriatric patients. 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)

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

510(k) Number K021895

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

(Optional Format 1-2-96)