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SECTION 2: SUMMARY AND CERTIFICATION
510(K) SUMMARY

Safety and effectiveness information concerning the Bio-logic Evoked Potential product and this device modification 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: March 17, 2003

NAME OF DEVICE: Stacked ABR for Navigator Pro.

COMMON NAME: Evoked Response System.

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

PREDICATE DEVICE: Bio-logic Navigator Pro, 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 display of human physiological data for auditory testing purposes and to assist in determining possible auditory and hearing-related disorders. . The predicate device referenced above is the latest in a series of systems of this type marketed by Bio-logic.

The Navigator Pro Evoked Potential Predicate Device performs ABR recording functions with two channels of simultaneous data recording. The software for the Navigator Pro implements the standard Auditory Brainstem Response (ABR) functions common to most similar systems on the market for many years. One of these functions is the testing for auditory nervous system abnormalities but these measures are only effective once the abnormality has sufficiently progressed so as to affect a large number of fibers in the auditory nerve. The Stacked ABR for Navigator Pro device provides software additions to the Predicate Device for the purpose of displaying ABR activity

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affecting a subset of the nerve. These additional features include automated masking, filtering and data manipulation functions, which allow the observation of ABR test results for frequency band subsets of the nerve fibers in addition to the fibers as a whole.

The standard ABR test works on the basis of repeating a stimulus-response cycle. An auditory stimulation (click, tone, etc.) is presented to the patient through the use of an earphone or headphones. The EEG response from the brain is read through the use of one or more scalp electrodes placed on the patient. The response time of interest is approximately from 1 – 20 milliseconds following the stimulus. The response voltage readings for this time period are amplified, digitized and stored in the AEP system computer's memory. The stimulation is then repeated, the EEG response is read again, and this cycle is repeated many times . Each time the response is read, it is averaged together with all previous responses. The final data record is the result of averaging several thousand (usually 2000-3000) responses. This averaging process is necessary because the ABR signal is very small, much lower in voltage than the surrounding EEG "noise" present in the recording. The noise is averaged out over the many readings, because the noise will have a very low average net value. The result from the averaging process will be the signal.

The response generated from the standard ABR test is comprised of contributions from all fibers, that is, all frequency regions of the auditory nerve. Although all frequency regions contribute to the standard click-evoked ABR, its morphology is dominated by the high frequency fibers of the nerve because the contributions of the lower frequencies that would appear at longer latencies in the response are largely phase-cancelled.

Medium and large acoustic abnormalities that affect a large number of nerve fibers impact the standard ABR by changing the response parameters of the various ABR waveform landmarks. Abnormalities that impinge only on a region of nerve fibers, especially the low frequency fibers, often have no impact on the standard ABR measurements because the standard ABR is dominated by the healthy, high frequency fibers. ABR tests which provide electrophysiological data based on the response from all of the nerve fibers all at the same time do not attempt to isolate the responses of the low frequency fibers from those of the high frequency fibers.

The Stacked ABR device, the purpose of this 510(k), collects several ABR waveform responses, each representing the contribution of subsets of fibers in the acoustic nerve. It does this by collecting first a standard click alone ABR. Five additional ABRs also are collected using a stimulus comprised of the click mixed ipsilaterally with a high-pass filtered masking noise. The cut-off frequency of the high-pass noise is successively lowered from one run to the next in octave steps from 8kHz to 500 Hz. The portion of the auditory system that is masked by the noise does not contribute to the ABR. After the ABRs are collected, the derived band technique, a simple waveform subtraction process that has been used in humans for more than 25 years, is used on successive pairs of the ABR responses to derive the contribution from small frequency regions of the auditory nerve. The most prominent landmark, the peak of Wave V, is then identified in the derived bands. Since Wave V latency is affected by frequency, the Wave V peak in the derived bands will be later for lower frequency regions than for high frequency regions. In order to avoid the phase cancellation issues present in standard ABR, the Wave V peaks of the derived bands are aligned temporally before being summed to obtain a total response. This response equally reflects the contributions of all frequency regions of the auditory nerve. This is the Stacked ABR. The peak to trough amplitude of Wave V of the Stacked

ABR can be compared to normative data or to the patient's other ear to determine whether referral for further diagnostic tests are required.

The Stacked ABR technique is a data manipulation of derived-band responses. It is possible to perform all of these manipulations using existing manual techniques in the Bio-logic Navigator Pro Evoked Potential Predicate Device. The Stacked ABR software simply automates the masking, filtering, time-shift/alignment and summing processes described above, to quickly achieve a new overall ABR more representative of the patient's hearing across all frequency bands.

In addition to the data manipulation techniques described above, Stacked ABR also uses noise estimation techniques to stop collecting data for averaging when the estimated residual noise level reaches a pre-selected low value. Standard ABR techniques stop the averaging process after a pre-selected number of stimulus-response cycles (sweeps). In the case of Stacked ABR, after each block of sweeps, the value of the averaged background noise for that block is estimated. Those blocks with lower noise are considered to be of higher quality than those with higher background noise, and are therefore weighted more heavily in the averaging process than those with higher noise. When the residual background noise in the average gets down to the pre-selected low level, the averaging stops. This results in a reduction of the effect of variations in the averaged physiological background noise on the interpretation of the ABR recordings.

INTENDED USE:

The Bio-logic Evoked Potential (EP) product family is indicated for use in the recording and display of human physiological data, for auditory testing purposes and to assist in determining possible auditory and hearing-related disorders. Auditory stimuli are presented to the patient's ear through an earphone or headphones, and the corresponding Auditory Brainstem Responses (ABR) from the patient are recorded using EEG electrodes placed on the scalp. Standard ABR testing is most used clinically for 2 reasons: (1) to predict behavioral audiometric thresholds, and (2) as an audiological testing tool to assist in the assessment of possible auditory nervous system abnormalities.

The Bio-logic Navigator Pro EP System 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.

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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, ISO-13485 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 for the Stacked ABR for Navigator Pro was written in accordance with ISO-14971, the International Standard: Application of Risk Management to Medical Devices.

The Stacked ABR for Navigator Pro software does not make any final decisions that result in any automatic forms of diagnosis or treatment. All program "recommendations" are subject to review by the EP Technologist or Physician, and may be modified, overridden or deleted as determined by a qualified user. The program provides additional functionality to allow the qualified user to review all raw data collected and perform other data analysis to suit his or her requirements.

The chart below provides a summary comparison of the technological characteristics of the new Stacked ABR device relative to the predicate Navigator Pro device. This is to demonstrate that this new Stacked ABR for Navigator Pro device has no significant differences which would adversely affect product safety and effectiveness.

Parameter for comparison	Similarity or Difference
Intended Use	No differences.
Population	No differences.
Hardware Configuration	No differences.
Computer Control Software	The Stacked ABR for Navigator Pro software is built on the Navigator Pro software of the Predicate Device. There are new automated features added to implement derived-band ABRs, time-shifting and alignment to enhance the wave V responses, termination of averaging based on estimated residual noise level, and weighting the averages with lower noise more highly than those averages with higher noise.
Patient information and tracking.	No differences.
Patient connections (transducers and electrodes)	No differences.
Presentation of Data / User Interface	The User Interface is essentially the same, except that the presentation of data includes the Stacked ABR program options.
Physical Characteristics	No differences.
Safety Characteristics	No differences. The basic patient connection and isolation circuits are the same for both products.
Product Labeling	No differences.
Anatomical sites.	No differences.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

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

Re: K030907
Trade/Device Name: Stacked ABR for Navigator Pro
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ
Dated: April 18, 2003
Received: April 21, 2003

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), 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) you may obtain. 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

K030907

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030907

Device Name: Stacked ABR for Navigator Pro - Modification to Bio-logic Evoked Potential.

Indications For Use:

The Bio-logic Evoked Potential (EP) product family is indicated for use in the recording and display of human physiological data, for auditory screening purposes and to assist in determining possible auditory and hearing-related disorders. Auditory stimuli are presented to the patient's ear through an earphone or headphones, and the corresponding Auditory Brainstem Responses (ABR) from the patient are recorded using EEG electrodes placed on the scalp. Standard ABR testing is most used clinically for 2 reasons: (1) to predict behavioral audiometric thresholds, and (2) as an audiological testing tool to assist in the assessment of possible auditory nervous system abnormalities.

The Bio-logic Navigator Pro EP System 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)

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

(Optional Format 1-2-96)

2003 APR 21 A 9:38

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030907