



DEC 27 1999

K 994149

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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
One Bio-logic Plaza
Mundelein, IL 60060

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CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: December 3, 1999

NAME OF DEVICE: Bio-logic ABAER / Navigator Pro.

COMMON NAME: Evoked Response System.

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

PREDICATE DEVICE: Bio-logic Evoked Potential for ABAER I,
reference 510(k) #K992807.

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 systems of this type marketed by Bio-logic. Other related devices comprising 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.

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The Predicate Device performs Evoked Potential recording and analysis functions, provides two channels of simultaneous data recording, and includes the option of applying the Point Optimized Variance Ratio (POVR) algorithm for optimizing signal quality and speed of test completion. This new device has both hardware and software modifications and improvements over the Predicate and related devices. Related Device #1 above is the first Evoked Potential device marketed by Bio-logic. It provides for up to 4 channels of data recording. Related Device #2 above is a hardware/software modification to the first device. Related Device #3 above is similar to #2, but utilizes a “portable” computer for ease of use and transportability. Device #4 utilizes hardware and software variations over devices #1, #2 and #3, primarily to enhance size-reduction and portability. It provides for a maximum of 2 channels of data recording. Trade names of “Traveler”, “Express” and “LT” are associated with these transportable devices. Device #5 incorporates the “Explorer” hardware with corresponding hardware control and analysis features in the software. Data recording hardware is available in three variations: the “E” Series, for up to 2 channels of data recording; the “SE” Series, for up to 4 channels of data recording; and the “Explorer” Series, for up to 8 channels of data recording. The Evoked Potential software has stayed essentially the same for all of these products, with variations in models to accommodate differences in the hardware.

Evoked Potential systems can be used for three different kinds of tests: Auditory Evoked Potentials (AEP), Visual Evoked Potentials (VEP), and Somatosensory Evoked Potentials (SEP). These variations are called “modalities”, and are offered as options in all three models of hardware marketed by Bio-logic. Each modality has its own unique hardware requirements. The changes described in this 510(k) are to incorporate a repackaged variation of the previously-described “E” Series hardware (2-channel), along with a new Windows-based software program for the control of this new hardware. This hardware performs the AEP test only, so, correspondingly, the software contains only AEP control and analysis features.

The AEP 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 EEG 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 an average net value of zero. The result from the averaging process will be the signal.

Some of the EEG responses may have large amounts of noise or other artifact caused by random events such as patient movement or externally-generated electrical noise. These artifacts are usually characterized by very high amplitude voltages (relative to normal EEG levels). The EP program automatically monitors the response for abnormally-high voltage levels. When a response contains such artifacts, the response is discarded, not averaged, and not counted in the cycle count.

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The Predicate Device describes the use of the POVR algorithm to monitor the signal-to-noise ratio of the averaged response signal every 256 stimulation-response cycles. This modified device, ABAER / Navigator Pro, incorporates the same POVR algorithm for the same purpose, to yield high-quality test results in the shortest possible time. In addition, the feature modifications for this new device include the use of a redesigned hardware package (called the Navigator Pro) and a Windows-based software program to control the hardware. The functions of the hardware are substantially the same as those of the Predicate Device hardware. The software for control of this device is a simplified subset of the DOS-based Predicate Device software. Together, they implement the same functionality and perform the same intended use as the Predicate Device, but with improved ease-of-use.

The Navigator Pro hardware is very similar in electronics design to the Navigator E hardware used in the Predicate Device, except that the electronics hardware has been re-packaged into a stand-alone box which derives its power from a separate medical-grade power supply and connects to the host computer through a serial port. In the Predicate Device, the Navigator E hardware consists of two ISA-bus computer boards mounted inside the host computer and connected to an external patient-connection module through a dedicated cable. The ISA computer bus is no longer fully supported by many computer makers, and many new computers do not have any ISA slots at all. Also, because computers are getting smaller and many (such as laptops) do not have any expandable internal bus at all, this new Navigator Pro hardware design offers more flexibility and options for use than does the present Navigator E hardware. Nearly all computers have at least one serial port, which is all that is necessary to connect to the Navigator Pro hardware.

The host software for the Predicate Device is DOS-based, whereas the host software for the ABAER – Navigator Pro (subject of this Special 510(k)) is WINDOWS-based. The WINDOWS program has much of the same functionality as that of the predicate device, but with improved user interfaces and overall ease-of-use. Because the primary intention of the ABAER program is one of simplified testing and screening, some of the more complex diagnostic functions of the Predicate Device were removed to make the device easier to use.

INTENDED USE:

The Bio-logic Evoked Potential (EP) product family is intended for use in the recording and analysis of human physiological data necessary for the diagnosis of auditory and hearing-related disorders. An auditory stimulus (click, tone, etc.) is presented to the patient's ear through an earphone or headphones, and the Brainstem Auditory Evoked Response from the patient is recorded using EEG electrodes placed on the scalp. Although this Brainstem Response is very low in amplitude (with respect to surrounding EEG "noise"), the stimulus-response cycle is repeated many times and the resulting responses are averaged from the time of the stimuli. The random noise averages to zero, but if the Brainstem Response signal is present, it's signal will be easily determined in the averaged signal.

The Bio-logic AEP System 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 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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The ABAER with Navigator Pro device uses a redesigned hardware package and a Windows-based software program to control the hardware. The functions of the hardware are substantially the same as those of the Predicate Device hardware. The software for control of this device is a simplified subset of the DOS-based Predicate Device software. Together, they implement the same functionality and perform the same intended use as the Predicate Device, but with improved ease-of-use. The POVR algorithm described in the Predicate Device is implemented in the new Windows software to generally assist in test data interpretation, and specifically assist in the assessment of signal-to-noise ratio and the quality of the Brainstem Auditory Evoked Response in infants. Based on this automatic assessment, the speed of testing may be reduced and/or the quality of the data recording may be improved, without compromising the quality of recorded data or limiting the control and flexibility of the health care professional administering the test.

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 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 ABAER / Navigator Pro design.

The Navigator Pro patient-connection hardware utilizes many of the same design principles and circuit designs as are used in the Bio-logic Evoked Potential "E" series hardware. 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. The Navigator Pro utilizes a medical-grade power supply, whereas the "E" Series hardware used the computer's power. 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, instead of directly from the host computer program. By distributing the hardware-specific functions to the DSP, the Windows-based host computer program has fewer real-time demands, and performance and reliability are improved.

The ABAER / 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 on the following page provides a summary comparison of the technological characteristics of the new modified device relative to the predicate Evoked Potential device. This is to demonstrate that this new ABAER / Navigator Pro device has no significant differences which would adversely affect product safety and effectiveness.

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Parameter for comparison	Similarity or Difference
Intended Use	No differences.
Population	No differences.
Hardware Configuration	Predicate Device uses Navigator E hardware, whereas the new ABAER product uses Navigator Pro hardware. The two hardware types are similar in functionality, patient connection, and patient isolation circuits.
Computer Control Software	Predicate Device software is DOS-based, whereas the new ABAER product uses a combination of Windows-based host software and a DSP hardware control program in the Navigator Pro module.
Patient information and tracking.	The new ABAER program incorporates an EXCEL-compatible database for Patient and Test Information, which represents an extensive improvement in performance over the DOS filename-based method of the Predicate Device.
Test Performance – Time to Complete.	No significant differences.
Test Performance – Data Quality.	No significant differences.
Safety Characteristics	No differences. The basic patient connection and isolation circuits are the same for both products.
Product Labeling	The labels used on the two products are different primarily because of the different physical characteristics of the two hardware types. Also, the new ABAER / Navigator Pro label makes use of standard international symbols for patient and device connections.
Anatomical sites.	No differences.
Physical Characteristics	The new Navigator Pro hardware is physically different from that of the Predicate Device. It is housed in a separate module with its own separate medical-grade power supply, and connected to the host computer via serial port. Predicate Device Series “E” hardware has boards inside the computer and a separate patient-connection module.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994149
Trade Name: ABAER/Navigator Pro Evoked Potential
Regulatory Class: II
Product Code: GWJ
Dated: December 6, 1999
Received: December 8, 1999

Dear Mr. Brunner:

We have reviewed your Section 510(k) 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). 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.

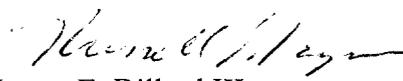
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Norman E. Brunner

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


86- James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Device Name: Modification to Bio-logic Evoked Potential for ABAER / Navigator Pro.

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. An auditory stimulus (click, tone, etc.) is presented to the patient's ear through an earphone or headphones, and the Brainstem Auditory Evoked Response from the patient is recorded using EEG electrodes placed on the scalp. Although this Brainstem Response is very low in amplitude (with respect to surrounding EEG "noise"), the stimulus-response cycle is repeated many times and the resulting responses are averaged from the time of the stimuli. The random noise averages to zero, but if the Brainstem Response signal is present, it's signal will be easily determined in the averaged signal.

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

The feature modifications represented in this Special 510(k) are for the use of a redesigned hardware package and a Windows-based software program to control the hardware. The functions and electronic design of the hardware are substantially the same as those of the Predicate Device hardware. The software for control of this device is a simplified subset of the DOS-based Predicate Device software. Together, they implement the same infant hearing screening functions and perform the same intended use as the Predicate Device, but with improved ease-of-use. The POVR algorithm described in the Predicate Device is implemented in the new Windows software to generally assist in test data interpretation, and specifically assist in the assessment of signal-to-noise ratio and the quality of the Brainstem Auditory Evoked Response in infants. Based on this automatic assessment, the speed of testing may be reduced and/or the quality of the data recording may be improved, without compromising the quality of recorded data or limiting the control and flexibility of the health care professional administering the test.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin S. Payne 545211
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994149

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)