



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 - 2004

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

Re: K974076

Trade/Device Name: Sport/AuDX OAE Test Instrument with Bio-logic Ear Probe
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: II
Product Code: EWO
Dated: April 20, 2004
Received: May 13, 2004

Dear Mr. Brunner:

This letter corrects our substantially equivalent letter of January 22, 1998 regarding the product name.

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 determining cochlear function by measuring and recording transient (click-evoked) otoacoustic emissions (TEOAE) or by measuring and recording distortion product otoacoustic emissions (DPOAE) utilizing continuous pure tones 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 (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.

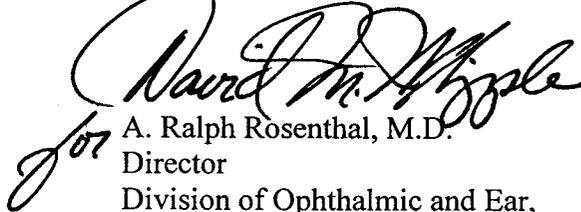
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "David M. Wipple". The signature is written in black ink and is positioned above the typed name and title.

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

K974076

SAFETY AND EFFECTIVENESS SUMMARY

JAN 22 1998

The Scout Sport/AuDX OAE Test Instrument with Bio-logic Ear Probe is a battery-operated device which connects to the patient's ear using the new Bio-logic Ear Probe. There are no metallic parts which touch the patient in the normal use of this device. The power supply / battery charger supplies 12 volts DC to the Sport OAE box when it is connected, and this charger is UL and CSA listed with a leakage current of less than 100 microamps. Therefore, there is no electrical hazard or danger to the patient when using this device. In this respect, it is exactly the same as the predicate device.

During normal OAE testing, the Scout Sport is connected to the computer running the Scout software through a standard RS-232 serial data communications link. The AuDX is not connected to the computer in normal operation, but may be connected as the Sport during setup and data downloading. There are two types of computer which can be used for this purpose.

1. If the computer is a battery-powered laptop with no connection to the AC line source, there is no voltage present in the system which can inflict serious harm to the patient, so no special patient isolation is required.
2. If the computer is an AC-powered system, such as a desktop unit, a separate isolation transformer is used to provide for leakage current levels below 100 microamps.

Because of the low-voltage and isolated nature of the hardware design, as well as the lack of any direct electrical patient connection, there are no failure modes in the Scout Sport/AuDX software which can cause the hardware to cause injury to the patient. The overall unit is designed to withstand the electrical environments found in hospital and clinical situations, including interference from other electrical devices and static electricity.

To establish the safety and effectiveness of the software which controls the Scout Sport/AuDX OAE Test Instrument with Bio-logic Ear Probe, the system was validated in accordance with the Bio-logic internal software development policies and procedures modeled after the IEEE Standards. The programs in the Scout Sport/AuDX were developed and tested as specified in these procedures. The system, for which this application is submitted, was verified and validated; it was found to perform in accordance with specifications.

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

Device Name: SPORT/AUDX OAE TEST INSTRUMENT WITH BIO-LOGIC EAR PROBE

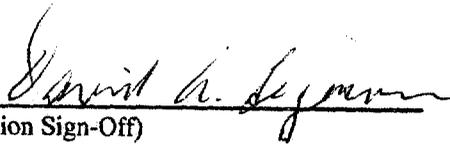
Indications For Use:

The Bio-logic OAE Ear Probe is used as an accessory to the Bio-logic SCOUT Sport and AuDX Otoacoustic Emissions Test Instruments. These instruments are identical to each other in purpose, and are indicated for use when it is necessary for a trained health care professional (for example, an Audiologist) to measure or determine cochlear function. This test consists of either measuring and recording transient (click-evoked) otoacoustic emissions (TEOAE) or by measuring and recording distortion product otoacoustic emissions (DPOAE) utilizing continuous pure tones. The same Ear Probe is used with both instruments for both types of test.

It can be used for patients of all ages, from newborn infants through adults, to and including geriatric patients. The otoacoustic emissions test 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.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K994076

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)