

K061744

510(k) Summary of Safety and Effectiveness

SEP 15 2006

**510(k) Summary of Safety and Effectiveness
as required by section 807.92 (c)**

Submitters Name and Address: Bio-logic Systems Corp.,
(a Natus company)
One Bio-logic Plaza
Mundelein, IL 60060

Contact Person & Phone: Mr. Norman Brunner
(847) 949 5200 ext. -224

Date Summary Prepared: May 05th, 2006

Device Name: Classification name – Audiometer, EWO
Proprietary / Trade name: Cochlea-Scan / Cochlea-Scan Plus

Predicate Device: Fischer-Zoth, model Echo-Screen: 510(k) K013977

Device description:

Cochlea-Scan is a hand-held examination system based on Otoacoustic Emissions (OAE) technology. Identical techniques are used – among others - on Fischer-Zoth model Echo-Screen. The Cochlea-Scan product family is designed easy to use and employs automated OAE. The measurement flow is menu guided and the evaluation is based upon signal statistics. The Cochlea-Scan devices are designed for trained personnel in a medical or school environment to examine hearing in newborns through adults, including geriatric patients. With its built-in automated hearing threshold estimation algorithm the device does not measure hearing per se, but helps to determine whether or not a hearing loss may be present and in case of hearing loss proposes an estimation of the hearing threshold in a given frequency range. Additionally Cochlea-Scan is equipped with a standard pure tone audiometer.

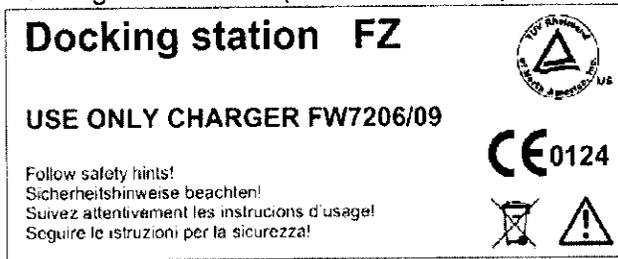
Intended use:

1. The Cochlea Scan is intended for use in automated objective hearing assessment using distortion product OAEs.
2. The Cochlea Scan is intended for use in diagnostic hearing evaluations and assistance in the diagnosis of possible hearing disorders by means of OAEs and/or pure tone audiometry. Hearing disorders include middle ear and cochlear hearing losses.
3. The results of the Cochlea Scan can be used to assist in the selection and/or (first-) fit of conventional hearing aids. It does not provide data for prescribing or fitting cochlear implants or middle ear implants.
4. The Cochlea Scan is intended for use in hearing screening using OAEs (with optional TEOAE module).

Technological Characteristics:

- Probe: miniature probe, easy to apply even for premature infants, identical to the probe used on the predicate device Echo-Screen
- Headphone: standard audiometry headphone with calibration data stored in customized connector

Docking station label (50 mm x 20 mm):



Operation manual

See Appendix A

Advertising and Promotional Materials

Bio-logic intends to promote and market the Cochlea-Scan in professional and trade publications, through marketing materials, and at trade shows and professional organization meetings. The advertising and promotional materials will incorporate the product design, product specifications, and product claims as described in this 510(k) submission.

All advertising and promotional materials will comply with the following statement of intended use:

The Cochlea Scan is intended for use in automated objective hearing assessment using distortion product OAEs.

The Cochlea Scan is intended for use in diagnostic hearing evaluations and assistance in the diagnosis of possible hearing disorders by means of OAEs and/or pure tone audiometry. Hearing disorders include middle ear and cochlear hearing losses.

The results of the Cochlea Scan can be used to assist in the selection and/or (first-) fit of conventional hearing aids. It does not provide data for prescribing or fitting cochlear implants or middle ear implants.

The Cochlea Scan is intended for use in hearing screening using OAEs (with optional TEOAE module).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2006

Bio-Logic Systems Corp.
c/o Mr. Norman Brunner
One Biologic Plaza
Mundelein, IL 60060-3700

Re: K061744
Trade/Device Name: Cochlea-Scan/Cochlea-Scan Plus
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: II
Product Code: EWO
Dated: August 18, 2006
Received: August 21, 2006

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

K061744

Device Name: Cochlea Scan.

Indications For Use:

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2. The Cochlea Scan is intended for use in diagnostic hearing evaluations and assistance in the diagnosis of possible hearing disorders by means of OAEs and/or pure tone audiometry. Hearing disorders include middle ear and cochlear hearing losses.
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use TVC
(Per 21 CFR 801.109)

TVC
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K061744

Prescription Use ✓

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)