K070696

JUN 29 2007

510(K) SUMMAREY OF SAFETY AND EFFECTIVENESS
Interacoustics ASSR, Eclipse System

SUBMITTER INFORMATION

A	Company Name:	Interacoustics A/S
B	Company Address:	Drejervaenget 8 Assens, DK-5610, Denmark
C	Company Phone:	+45 6371 3555
	Company Fax:	+45 6371 3522
D	Contact Person:	Hanne Nielsen Quality Manager Interacoustics A/S
E	Date Summary Prepared:	28/02/2007

DEVICE IDENTIFICATION

A	Generic Device Name:	Evoked Response Auditory Stimulator
B	Trade/proprietary Name:	Interacoustics ASSR, Eclipse System (cabinet name)
C	Classification:	Class II
D	Product Code:	GWJ

SUBSTANTIAL EQUIVALENCE

Predicate Device	**Manufacture**	**510(k) No.**	**Date Cleared**
Bio-logic Master Evoked Response System	Bio-logic Systems Corp	K021895	07/01/2002

DEVICE DESCRIPTION

This system consists of a general hardware platform (ERA) and a software platform (ASSR). This may be installed into any external cabinet as required for proper use of the system. For this application the external cabinet used is the Eclipse. Other cabinets will be released in the future using the same hardware platform (ERA) and will allow software interchange ability between cabinets.

As stated before this device is based on a general hardware platform (ERA) which is designed to be able to perform different audiometric and ABR testing functions. This module has been previously approved per 510k #K052562, functions may be added to this platform in the future, each module will be re-applied for at that time.

A license system makes it possible to select which functionality the user wants to be incorporated in the system.

The specific functionality of the system is controlled by the ASSR software. This software is installed on the connected PC and the system uses a USB connection between the PC and the hardware

Test results and reports are formatted and printed by the ASSR software. A database containing test results and other patient information can be located and shared on the PC.

INTENDED USE

The Interacoustics ASSR is indicated for use in the recording and analysis of human physiological data used for the diagnosis of auditory and hearing-related functions.

It allows for the estimation of hearing threshold at various frequencies, through the use of 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.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Interacoustics ASSR – Eclipse System and the predicate device has been performed. The results of this comparison demonstrate that the Interacoustics ASSR – Eclipse System is equivalent to the marketed Predicate device.

PERFORMANCE DATA

The performance data indicated that the Interacoustics ASSR – Eclipse System meets all specified requirements, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Interacoustics A/S
c/o Mr. Daniel Egan
Manager of Quality and Regulatory Compliance
7625 Golden Triangle Drive
Eden Prairie, MN 55344

Re: K070696
Trade/Device Name: Interacoustics ASSR, Eclipse System (Cabinet Name)
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: May 22, 2007
Received: May 23, 2007

Dear Mr. Egan:

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,

M B Eydelman, MD

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

K070696

Indications for Use Statement

Applicant: Interacoustics A/S

510(k) Number (if known): K070696

Device Name: Interacoustics ASSR

Indications For Use:

The Interacoustics ASSR is indicated for use in the recording and analysis of human physiological data used for the diagnosis of auditory and hearing-related functions.

The Interacoustics ASSR can be used as either simple screening device, or a diagnostic device if used as part of a group of audiometric tests. It is exceptionally useful in testing individuals for whom behavioural audiometric results are deemed unreliable; this would include infants, young children, cognitively impaired or uncooperative adults. It allows for the estimation of hearing threshold at various frequencies, through the use of ASSR (Auditory Steady-State Response) test protocols. It is designed to be used 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.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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James K. Kane, Ph.D
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises
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(Per 21 CFR 801.109)

Prescription Use X
(Per 21 CFR 801.109)