

K090406



Eclipse EP15/EP25 510(k) Summary

JUL 22 2009

Sponsor

Interacoustics A/S
Drejervaenget 8
DK-5610 Assens
Denmark

Phone: +45 63713555
Fax: +45 63713522

Contact person: Mrs. Hanne Nielsen
Preparation date: 03 Feb. 09.

Device

Trade names: EP15 software module, EP25 software module.
Common name: Audiometer
Classification name: EWO, GWJ

Predicate device

Eclipse (Cabinet name), TEOAE25, EP15, EP25 or the combination of the systems.
K052562

Device description

The EP15 and EP25 systems measure auditory brainstem responses picked up by skin electrodes and amplified by a pre amplifier. The data acquisition of the ABR recordings takes place from the surface electrodes mounted at specific recording points on the patient. The analogue ABR recordings are amplified in the external preamplifier connected to the electrodes. The amplified analogue ABR recordings are converted into a digital signal in the ADC (Analog to Digital Converter) inside the Eclipse. The digital ABR recordings undergo data processing handled by the PC to improve the ABR-recordings. The ABR-recordings are displayed on the monitor for the operator, for further examination and diagnosis. All ABR recordings are stored on the Laptop / Desktop computer hard drive for later examination and diagnosis.

Intended use

The Interacoustics EP systems, EP15 and EP25, are intended to assist in the evaluation, documentation and diagnosis of ear disorders on human beings. EP15/25 is a 2 channel ABR and the automatic recording of ABR waveforms makes it well suited for waveform based screening and the manual programmability options allow for comprehensive clinical use ranging from frequency specific threshold test to operating room applications and cochlear implant tests. The EP15 is a basic unit allowing only recording of the Auditory Brainstem Response

(ABR), while the EP25 allows recording of the ABR and earlier and later potentials.

The Interacoustics TEOAE25 system is intended for determining Cochlear function using Transient Evoked Otoacoustic Emission click stimuli.

Both of these systems are of particular interest to Ear, Nose, and Throat doctors, Neurology specialties, Audiologist and other health professionals concerned with measuring auditory functions.

Summary

The technological characteristics of the predicate device and modified EP15/EP25 system are listed in the table below.

	Predicate device	Modified device
Name	Interacoustics Eclipse	Interacoustics Eclipse
Model	EP15/EP25	EP15/EP25
K-number	K052562	
Clinical purpose	Measuring evoked potentials to assist in evaluation, documentation and diagnosis of hearing disorders in human beings.	Same as existing EP15/EP25
Patient group	New born to geriatric	Same as existing EP15/EP25
Test types	ABR, MLR, LLR, P300, MMN, EcochG	Same as existing EP15/EP25 plus EABR
Stimulus	Click, Tone burst	Same as existing EP15/EP25 plus Chirp, NB Chirp and click from wave file
Averaging	Standard averaging	Same as existing EP15/EP25 plus Bayesian weighting and low pass filtering
Presentation	EEG, Normative latency, Latency, Latency calculation.	Same as existing EP15/EP25 plus Residual noise, FMP values, EcochG area
Result evaluation	Manually / subjective	Same as existing EP15/EP25
Hardware system	Eclipse connected to Laptop through USB, Insert earphones, external preamplifier with surface electrodes	Same as existing EP15/EP25
Transducers	Eartone ABR insert phone TDH39 (Optional) B71 (Optional)	Same as existing EP15/EP25
Electrodes	Surface electrodes on: - Low forehead - High forehead - Both mastoids	Same as existing EP15/EP25
Preamplifier	Channels: 1 or 2 A/D resolution: 16 bit	Same as existing EP15/EP25 but with improved CMRR and lower noise.
Operating system	Windows 98 Windows XP Windows 2000	Same as existing EP15/EP25 plus Windows Vista

	Predicate device	Modified device
Operators manual	Covers the Eclipse EP15/EP25, TEOAE25, DPOAE20 and ASSR	Same as existing EP15/EP25 plus description of the new features

Tests

The usefulness of the EABR protocol setup has been validated with a positive result. The correct implementation of the new stimuli, i.e. chirp, NB chirp and click from wave file, have been verified through bench testing which provided the expected results. The generated electrical output was consistent with the mathematically predicted output. The correct implementation of the Bayesian weighting and low pass filtering has also been verified through bench testing and the results were as predicted. The EP15/EP25's ability to run under windows Vista® has also been tested and no abnormal behavior was detected.

Conclusion

Based on the design control, the tests performed and the validation of the modified device we conclude that the modified device is both as safe and effective and performs as good as or better than the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Interacoustics A/S
C/O Hanne Nielsen
Drejervaenget 8
DK-5610 Assens
Denmark

JUL 22 2009

Re: k090406

Trade/Device Name: Eclipse EP15/EP25 ABR System
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ
Dated: May 29, 2009
Received: June 9, 2009

Dear Ms. Nielsen:

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.

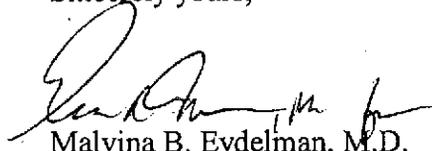
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K090406



Indications for Use

510(k) Number (if known): K090406

Device Name: TEOAE25, EP15 or EP25, or the combination of systems

Indications For Use:

The Interacoustics EP systems, EP15 and EP25, are intended to assist in the evaluation, documentation and diagnosis of ear disorders on human beings. EP15/25 is a 2 channel ABR and the automatic recording of ABR waveforms makes it well suited for waveform based screening and the manual programmability options allow for comprehensive clinical use ranging from frequency specific threshold test to operating room applications and cochlear implant tests. The EP15 is a basic unit allowing only recording of the Auditory Brainstem Response (ABR), while the EP25 allows recording of the ABR and earlier and later potentials.

The Interacoustics TEOAE25 system is intended for determining Cochlear function using Transient Evoked Otoacoustic Emission click stimuli.

Both of these systems are of particular interest to Ear, Nose, and Throat doctors, Neurology specialties, Audiologist and other health professionals concerned with measuring auditory functions.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Shulchan Berg
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Page 1 of 1

510(k) Number K090406