DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Interacoustics A/S, Assens
c/o Mr. Daniel Eggan
Manager of Regulatory Affairs/QA
Interacoustics USA
7625 Golden Triangle Drive
Eden Prairie, MN 55344

APR 29 2005

Re: K050496
Trade/Device Name: REM440
Regulation Number: 21 CFR 874.3310
Regulation Name: Hearing Aid Analyzer
Regulatory Class: Class II
Product Code: ETW
Dated: April 29,2005
Received: April 29,2005

Dear Mr. Eggan:

This letter corrects our substantially equivalent letter of April 29,2005 regarding the regulation number.

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 (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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.aovlcdrWdsma/dsmamain.html

Sincerely yours,

for Onette M Beers PhD

David M. Whipple
Acting Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section A

Indications for Use Statement

Applicant: Interacoustics A/S

510(k) Number (if known): K050496

Device Name: REM440, (for use with Thor Platform System Products)

Indications For Use:

The REM440 system is intended to be used as a system to perform Real Ear Measurement and assist in the adjustment of hearing aids while in use by the patient.
It is used by ENT-professionals and in clinics for hearing aid fitting.
This device can either be sold individually or together with other Thor Platform modules in the same housing.

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

Con. Evaluation (ODE)

(Per 21 CFR 801.109)

Prescription Use 4/29/05
(Per 21 CFR 801.109) K050496

4/29/05
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K050496