K083780

audio TECHNOLOGIES

ANNEX A → **510(K) SUMMARY** Page 1/1

MAR 2 3 2009

Trade name: Audio Prosthesis- Audio Technologies
Common name: Prothesis for otosurgery
Classification name: Partial Ossicular Replacement Prosthesis
Total Ossicular Replacement Prosthesis

submitter: AUDIO TECHNOLOGIES S.r.l.
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Date prepared: November 25th, 2008

predicate devices:
The *Audio Prosthesis - Audio Technologies*, are substantially equivalent to *Richards - marketed by Smith & Nephew*, and/or *Xomed - marketed by Xomed*, and/or *Exmoor - marketed by Exmoor Plastics and also Audio Technologies prosthesis.*

Description:
Otosurgical prosthesis of the middle ear, implanted, in a permanent manner, in patients affected with pathologies of the middle ear.
Otosurgical prosthesis of the middle hear, are manufactured from a wide variety of materials: platinum (Pt), titanium, poliethylene (PE), stainless steel, hydroxylapatite (HA), politetrafluoroethylene (PTFE), gold, polimetilxilossano (silicon) and Nitinol, or combination of these materials.
Numerous designs are available for replacement of any or all of the bones of the ossicular chain.

Intended use:
For replacement for any or all of the bones of the ossicular chain in the middle ear

Indications for use
Audio prostheses are successfully employed in case of otosclerosis, stapedo-vestibular ankylosis, outxome of otitis media, trauma, middle ear congenital malformations. Possible complication due to the use of prostheses in the middle ear include: fixation, displacement, extrusion of the prosthesis, incus necrosis, tympanic membrane perforation, perilymph fistula, labyrinthitis, otitis media, occlusion of oval and round window.
Some of the prostheses are manufactured in different lengths, some others shall be trimmed during the surgical operation. Nevertheless the length of all the prostheses should be carefully assessed by means of a microsurgical gauge (code 02.14)

Comparison to predicate devices:
These devices have the same indications for use (Partial / Total Ossicular Replacement Prosthesis, for reconstruction of the ossicular chain that has lost its function, due to disease, trauma, or congenital defect), the same technological characteristics, i.e. materials (all widely accepted for middle ear reconstruction), and the same general design.
Slight design differences between Audio Technologies Prosthesis and the predicate devices should not affect the safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Audio Technologies S.R.L
c/o Franco Beoni
Via Vallera, 42
Piacenza, Italy 1-29100

MAR 2 3 2009

Re: K083780
Trade/Device Name: Total/Partial Ossicular Replacement Prosthesis
Regulation Number: 21 CFR 874.3495
Regulation Name: Total Ossicular Replacement Prosthesis
Regulatory Class: Class II
Product Code: ETA, ETB
Dated: March 3, 2009
Received: March 11, 2009

Dear Dr. Beoni :

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Section 4. Indications for use statement

Indication for Use

510(k) Number (if known): K083780
Device Name: Prosthesis for otosurgey
Indication For Use:

Otosurgical prosthesis of the middle ear, implanted, in a permanent manner, in patients affected with pathologies of the middle ear.
Audio prostheses are successfully employed in case of otosclerosis, stapedo-vestibular ankylosis, outxome of otitis media, trauma, middle ear congenital malformations. Possible complication due to the use of prostheses in the middle ear include: fixation, displacement, extrusion of the prosthesis, incus necrosis, tympanic membrane perforation, perilymph fistula, labyrinthitis, otitis media, occlusion of oval and round window.
Some of the prostheses are manufactured in different lengths, some others shall be trimmed during the surgical operation. Nevertheless the length of all the prostheses should be carefully assessed by means of a microsurgical gauge (code 02.14)
The implant must be carried out by a qualified surgeon.

Prescription Use_____YES__ AND/OR Over-The-Counter Use_____NO__
(Part 21 CFR 801 Subpart D) (Part 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)

Karen Burke

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

510(k) Number K083780