K040996

AUG 2 0 2004

510(k) Summary

Submitter's Name Submitter's Address	Gyrus ENT LLC 2925 Appling Road, Bartlett, TN 38133
Submitter's Phone Number	(901) 373-0200
Contact Person	Alicia E. Farage
Date Revised:	April 14, 2004
Proprietary Name: Common Name: Classification Name:	RetroX Titanium Tube System Transcutaneous Titanium Tube System Transcutaneous Air Conduction Hearing Aid System (TACHAS) (§ 874.3950)
Classification	Class II
Classification Panel	Ear, Nose, Throat
Device Product Code	77 NIX

Subject Device Description

The RetroX Transcutaneous System is intended for use in patients with Mild to Moderate high-frequency hearing loss. The Titanium Tube System is placed via a "functional piercing" procedure through the soft tissue and serves as the conduit for amplified sound to the outer ear canal.

Applicable 510(k)s – Predicate Devices

Device	Manufacturer	FDA Clearance
RetroX TACHAS Titanium Tube System	Auric Hearing Systems	K013298

Subject Device Intended Use

The Transcutaneous Titanium Tube System has the same intended use as the original RetroX Transcutaneous Titanium Tube System: It is part of a hearing system for adults with Mild to Moderate high-frequency hearing loss.

510(k) Submission Exhibit 9 REVISED

Comparison Chart

Gyrus TACHAS Tube System vs. Auric TACHAS Tube System

	RetroX Transcutaneous Titanium Tube System (Gyrus ENT LLC)	**RetroX Transcutaneous Titanium Tube System** (Auric Hearing Systems, Inc.)
Intended Use	Hearing system for adults with Mild to Moderate high-frequency hearing loss.	Hearing system for adults with Mild to Moderate high-frequency hearing loss.
Material	Medical Grade Titanium Alloy	Medical Grade Pure Titanium
Number of Pieces for Tube	2	3
Various Sizes Available	Yes	Yes
Lengths Available	7, 10, 13, 16, 19, 21, 23, and 25 mm	15, 17, 19, 21, 23, and 25 mm
Diameter of Tube	2.5 mm	4.4 mm
How Supplied	Sterile	Non-Sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2004

Gyrus ENT
c/o Alicia E. Farage
Manager Clinical/Regulatory Affairs
2925 Appling Road
Bartlett, TN 38133

Re: K040996
Trade/Device Name: RetroX Titanium Tube System for RetroX Transcutaneous Air Conduction Hearing Aid
Regulation Number: 21 CFR 874.3950
Regulation Name: Transcutaneous Air Conduction Hearing Aid System
Regulatory Class: Class II
Product Code: NIX
Dated: August 12, 2004
Received: August 13, 2004

Dear Ms. Farage:

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Revised 6/04

510(k) Number: K040996
Device Name: RetroX Titanium Tube System for the RetroX Transcutaneous Air Conduction Hearing Aid System

Indications For Use:

- Mild to moderate high frequency hearing loss

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

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

510(k) Number K040996