510(k) Summary of Safety and Effectiveness

Trade Name:	SMart Offset Stapes Piston prosthesis
Common Name:	Middle Ear Piston
Classification Name:	Partial Ossicular Replacement Prosthesis (§ 874.3450)
Official Contact:	Gregory Sredin Manager of Regulatory Affairs Gyrus ENT 2925 Appling Road Bartlett, TN 38133
Telephone:	(901) 373-0200
Telefax:	(901) 387-3914
Date Prepared:	October 31, 2003

The SMart Offset Stapes Piston is substantially equivalent to the Angular Piston sold by Heinz Kurz GmbH Medizintechnik

Intended Use

The SMart Offset Stapes Piston has the same intended use as the Angular Piston: bridging the stapes in cases of otosclerosis: specifically for surgical revision in patients with a shortened incudal process, and also in primary surgery when this anatomical condition is present.

Material

The SMart Offset Stapes Piston differs from the predicate device in the material used. The predicate device used titanium whereas the SMart Offset Stapes Piston utilizes nitinol wire embedded in a fluoroplastic shaft. This is the same combination of materials that is utilized in the Gyrus ENT SMart Piston that was cleared by the FDA in K003214. ***(See Exhibit 6)***

K033554

510(k) Summary of Safety and Effectiveness

Trade Name:	SMart ISJ prosthesis
Common Name:	Partial Ossicular Replacement Prosthesis
Classification Name:	Partial Ossicular Replacement Prosthesis (§ 874.3450)

Official Contact: Gregory Sredin
Manager of Regulatory Affairs
Gyrus ENT
2925 Appling Road
Bartlett, TN 38133

Telephone: (901) 373-0200
Telefax: (901) 387-3914

Date Prepared: October 31, 2003

The SMart ISJ Prosthesis is substantially equivalent to the Angular Prosthesis (Plester) sold by Heinz Kurz GmbH Medizintechnik

Intended Use

The SMart ISJ Prosthesis has the same intended use as the Angular Prosthesis: bridging defects at the long incudal process with otherwise intact mobile chain.

Material

The SMart ISJ Prosthesis differs from the predicate device in the material used. The predicate device uses gold and titanium whereas the SMart Offset Piston utilizes nitinol shaft and loops welded to a titanium bell.

Table of Similarities and Differences

SMart Offset Stapes Piston vs. Angular Piston

	SMart Offset Stapes Piston (Gyrus ENT)	Angular Piston (Heinz Kurz GmbH Medizintechnik)	Similarities or Differences
Intended Use	Bridging the stapes in cases of otosclerosis: specifically for surgical revision in patients with a shortened incudal process, and also in primary surgery when this anatomical condition is present	Bridging the stapes in cases of otosclerosis: specifically for surgical revision in patients with a shortened incudal process, and also in primary surgery when this anatomical condition is present	Same. No new indications for use.
Loop material	Nitinol	Titanium	Different. Nitinol is also biocompatible and was chosen for its shape-memory characteristics that allow the surgeon to close the open loops around the incus using a heat source in addition to manual crimping.
Shaft material	Fluoroplastic	Titanium	Different. Fluoroplastic has a long history as an implant material and was chosen for its ability to be molded around the shaft of the loops
Lengths	3.0 mm through 6.0 mm (functional length)	6.0 mm (overall length)	Comparable. The SMart is offered in lengths of 3 – 6 mm, in 1-mm increments to assist the surgeon in selecting the optimal length for his patient
Shaft Diameter	.4, .6, .8 mm	.4, .6 mm	Comparable. In addition to the .4 and .6 mm shaft the SMart is also offered in a .8 mm diameter for the surgeon seeking more stability. Similar shaft diameters are found in the Gyrus ENT SMart Piston (K003214)
Offset	1mm to 2mm	2 mm	Comparable. The SMart piston will be offered in offset lengths between 1 and 2 mm to allow the surgeon greater flexibility in selecting the appropriate size for his patient.
How supplied	Sterile	Sterile	Same

K033554

SMart ISJ prosthesis vs. Angular Prosthesis

	SMart ISJ Prosthesis (Gyrus ENT)	Angular Prosthesis (Heinz Kurz GmbH Medizintechnik)	Similarities or Differences
Intended Use	Bridging defects at the long incudal process with otherwise intact mobile chain.	Bridging defects at the long incudal process with otherwise intact mobile chain.	Same. No new indications for use.
Loop material	Nitinol	Titanium	Different. Nitinol is also biocompatible and was chosen for its shape-memory characteristics that allow the surgeon to close the open loops around the incus using a heat source in addition to manual crimping.
Bell material	Titanium	Titanium/Gold	Same
Lengths of offset	2.25 mm, 3.25 mm	2.25 mm, 3.25 mm	Same
How supplied	Sterile	Sterile	Same

K033554

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2003

Gyrus, ENT L.L.C.
c/o Gregory Sredin
Manager of Regulatory Affairs
2925 Appling Road
Bartlett, TN 38133

Re: K033554
Trade/Device Name: SMart™ Offset Stapes Piston Prosthesis
SMart™ ISJ Prosthesis
Regulation Number: 21 CFR 874.3450
Regulation Name: Partial ossicular replacement prosthesis
Regulatory Class: Class II
Product Code: ETB
Dated: November 10, 2003
Received: November 12, 2003

Dear Mr. Sredin:

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

510(k) Number:
Device Name: **SMart Offset Stapes Piston Prosthesis**

Indications for Use:

- Bridging the stapes in cases of otosclerosis: specifically for surgical revision in patients with a shortened incudal process, and also in primary surgery with this anatomical condition.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K033554

510(k) Number:
Device Name: **SMart ISJ Prosthesis**

Indications for Use:

- Bridging defects at the long incudal process with otherwise intact mobile chain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K033554