AUG - 4 1997

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6. 510(k) SUMMARY

As required by Section 807.92(c)

(1) Submitter [807.92(a)(1)]

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Business Support International
Amstel 320-I
Amsterdam, 1017AP
The Netherlands

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(2) Identification of Devices [807.92(a)(2)]

Trade Names	a. Bell Prostheses (Various Models)
	b. Angular Prosthesis (Plester)
Common Name	Partial Ossicular Replacement Prosthesis (PORP)
Classification Name	Middle-Ear, Prosthesis, Partial Ossicular Replacement
Product Code	77 ETB
Class	II
Regulatory Number	874.3450

(3) Identification of Predicate Devices [807.92(a)(3)]

The KURZ Bell ossicular implants are substantially equivalent to partial ossicular devices of Smith & Nephew Richards, Bartlett, TN, USA and Xomed, Jacksonville, FL, USA (which also markets Ionos devices); the Angular (Plester) is substantially equivalent to S&N Richards Applebaum Prosthesis. These devices have been found substantially equivalent through the 510(k) premarket notification process.

(4) Description of Device [807.92(a)(4)]

a. Gold (Bell) The implant consists of a golden wire rectangle or an extremely thin mesh plate with a structured outer surface and a stem which is available in ¼mm incremental lengths. It ends in a 'bell' with miniscule slits.

b. Titanium (Bell) The implant consists of a titanium mesh plate that is textured on the surface that faces the tympanum. A bell with four slits and a textured inner side is located at the upper end of the shaft.

510(k) Summary (Cont'd)

c. **Angular** The Angular prosthesis (Plester) consists of a slit bell, an angular stem (both Au), and two (2) titanium clamps at its end. The open ends of the titanium clamps are slightly staggered, so that they do not touch each other.

The devices are implants for single patient use. They come in an individual sterile package in a sealed carton.

(5) Intended Use of Device [807.92(a)(5)]

a. **Bell Implants** (Gold and Titanium)
The KURZ Bell implants are intended for partial replacement of the ossicular chain to facilitate conduction of sound energy from the ear drum to the inner ear. The prostheses are implanted into the middle ear during a tympanoplasty procedure and are retained in the middle ear by the design configuration of the devices and the favorable bio-compatible characteristics of gold and titanium.

b. **Angular Prosthesis (Plester)** (Gold with Titanium Bands)
The KURZ Angular Prosthesis is intended to bridge defects at the long incudal process and otherwise intact chain.

The devices can be used on adults and children.

(6) Technological Characteristics [807.92(a)(6)]
The implants can be bent and easily shaped to the individual conditions in the middle ear, yet hold their shape after placement.

(7) Information Bearing on the Safety and Effectiveness
The KURZ Bell and Angular partial ossicular replacement prostheses have the same intended use as predicate devices. There are no additional characteristics known that should adversely affect the safety and effectiveness of these implants.

Signature _____ Date _____
Dagmar S. Mäser Date

510(k) Number K972492

Device Name **Angular Prosthesis (Plester)**

INDICATIONS FOR USE:

For bridging defects at the long incudal process in patients with otherwise intact mobile chain.

The Angular prosthesis (Plester) consists of two titanium bands which are connected by a gold wire to the bell with its cross-shaped slits.

The bands function as clamps and are positioned on the long incudal process. In cases of arrosion at the distal end of the long incudal process, the prosthesis allows the reconstruction of the continuity of the auditory ossicular chain. By slight lateral displacement of one end of the bands overclosure is possible. Titanium ensures a firm connection with the bone.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972492

Prescription Use ✓ OR Over-The-Counter Use _____
(Per CFR 801 109)

(Optional Formal 1-2-96)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 1997

Dagmar S. Maser
Business Support International
Amstel 320-1
1017 AP Amsterdam
The Netherlands

Re: K972492
Partial Ossicular Replacement Prosthesis
Dated: June 20, 1997
Received: July 2, 1997
Regulatory class: II
21 CFR 874.3450/Procode: 77 ETB

Dear Mr. Maser:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K972492

Device Name Bell Prosthesis (Partial)

INDICATIONS FOR USE:

Ossicle replacement in case of interrupted sound conducting chain and intact, ~~mobile stapes footplate.~~

The Bell Prosthesis is intended for partial replacement of the auditory ossicles.

The bell is mounted on the head of the stapes, i.e. interposed between stapes and ear drum or stapes and manubrium mallei. Should stapes head no longer exist, bell is placed on intact arch of crus.

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

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510(k) Number K972492

Prescription Use ✓ OR Over-The-Counter Use _____
(Per CFR 801 109)

(Optional Formal 1-2-96)

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