K973356

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NOV 21 1997

6. 510(k) SUMMARY

As required by Section 807.92(c)

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

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

Proprietary Names	K-Piston; Angular Piston
Common Name	Middle Ear Pistons
Classification Name	Prosthesis, Partial Ossicular Replacement
Product Code	77 ETB
Class	II
Regulatory Number	874.3450

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

KURZ pistons are substantially equivalent in size and design to FDA-approved devices manufactured by Smith & Nephew Richards, Bartlett, TN, and XOMED, Jacksonville, FL, (which also markets TREACE devices). These devices have been found substantially equivalent through the 510(k) premarket notification process.

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

a. **K-Piston** Like many of the SE devices, the K-Piston is shaped like a bishop's crosier. Its outstanding feature is the slightly laterally displaced, wide golden band. The bent end allows overclosure and, thus, extremely secure fastening, around long process of incus.

b. **ANGULAR Piston**
An angled gold wire with two titanium bands, which are connected to the shorter leg. Specifically designed in cases of extreme arrosion of long incudal process.

Both devices are manufactured of fine gold (99.99%).

510(k) Summary (Cont'd)

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

a. **K-Piston** (Fine Gold)
For bridging the stapes in case of otosclerosis, also for bridging defects of the ossicular chain between manubrium mallei and vestibulum (malleovestibulopexy).

b. **ANGULAR Piston** (Gold with Titanium Bands)
For bridging the stapes of otosclerosis, specifically for surgical revisions in patients with shortenend incudal process and for primary procedures when this anatomical condition is present.

(6) **Technological Characteristics and Adjustments** [807.92(a)(6)]
The implants are manufactured of one piece of pure gold; the two bands on the short leg of the ANGULAR Piston of pure titanium (99.99%).

Within the range necessary for implantation, any part of the prosthesis can be bent back and forth up to three times.

Placement of the K-Piston requires bending of the loop to attach it to the long incudal process. Placement of the ANGULAR Piston requires bending of the titanium clamps for attachment to the incudal process stump. In addition, the preset 90° angle will have to be adjusted in many cases.

(7) **MRI Environment**
Testing in a 0.5 Tesla nuclear magnetic resonance tomograph has revealed no implant movement and no adverse tissue effects attributable to MRI-generated heating. The image quality may be impeded or blurred in direct vicinity of the implant. To date, no report of hearing loss or other adverse effect has come to the attention of the manufacturer.

(8) **Information Bearing on the Safety and Effectiveness**
The KURZ K-Piston and ANGULAR Piston 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 _____ Dagmar S. Maeser

10/20/97
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 1997

Ms. Dagmar S. Maeser
Business Support International
Amstel 320-I
1017 AP Amsterdam
The Netherlands

Re: K973356
Heinz Kurz GmbH Medisintechnik
Partial Ossicular Replacement Prosthesis
Dated: October 20, 1997
Received: October 22, 1997
Regulatory Class: II
21 CFR 874.3450/Procode: 77 ETB

Dear Ms. Maeser:

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,

William 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

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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) 594-4588. 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure