MAR - 8 2001

Heinz Kurz GmbH · Medizintechnik · Postfach 39 · D-72142 Dusslingen

K010442

Heinz Kurz GmbH
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2. 510(k) SUMMARY of Safety and Effectiveness

Heinz Kurz GmbH Medizintechnik

As required by Section 807.92(c)

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

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2.2 Contact Person: [807.92 (a)(1)]

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2.3 Date Summary Prepared: [807.92 (a)(1)]

February 1, 2001

2.4 Device Names: [807.92 (a)(2)]

Proprietary	Angular Piston - Titanium
Common	Middle Ear Piston
Classification	Middle Ear Prosthesis, Partial Ossicular Replacement
Product Code	77 ETB
Regulation #	CFR 874.3450

2.5 Reason for Submission:

Change in material and device length when compared to previously cleared device (s. 2.6, 2.7, 2.8, 2.12 and Comparison Table 2.13).

2.6 Modification to Existing Device: [807.92 (a)(3)]

K 973356 Angular Piston
(Pure Gold with two [2] Titanium Clamps)

2.7 Device Description: [807.92(a)(4)+(6)]

KURZ Angular Piston – Titanium consists of a round piston stem with a 90° handle, 2 mm in length, which carries two band clamps. Their open ends are slightly staggered so that they do not touch when closed. The clamps are designed to hold the stump of the long incudal process and serve to keep the prosthesis securely positioned. The piston enters the opened perilymphatic space through the stapes footplate.

The titanium pistons are substantially equivalent to the previously cleared devices with the following exceptions:

Material: The piston stem with 90° handle at upper end was changed
From Pure Gold
To ASTM F 67 Titanium

Length: [1] The all-titanium prosthesis will be available in three (3) lengths: 4.25, 4.50 + 4.75 mm while the SE gold/titanium prosthesis comes in one length only, 6 mm, which is adjusted to meet individual patient requirements.

The indications for use, piston diameters (0.4 + 0.6 mm), length of arm holding the clamps (2 mm + piston Ø), and the titanium band clamps for fastening to the stump of the incudal process are identical.

2.8 Reasons for Device Modification: [807.92 (d)]

Material:

1. Titanium provides excellent sound conduction even at higher frequencies;
2. Due to its lower specific weight[2] the device is substantially lighter than the gold/titanium angular piston

Length

Instead of the one, 6 mm, piston length, the new titanium prosthesis comes in three lengths:

4.25 4.50 4.75 mm

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[1] The 6 mm length of the gold/titanium angular piston was measured from the bottom of the piston up to the 90° angle, while the measurements of the titanium angular piston refer to the distance between the stapes footplate and the medial line of the incudal process stump.

[2] Gold: 19.3 kg/dm^3; Titanium: 4.5 kg/dm^3

The reason for this is that due to its specific material properties, titanium cannot be adjusted as easily as gold. The three (3) lengths were selected on the basis of clinical experience and should meet the requirements of more than 90% of patients indicated for this procedure.

2.9 Intended Use: [807.92 (a)(5)]

For bridging the stapes in case of otosclerosis; specifically for surgical revision in patients with a shortened incudal process, but also in primary surgery with this anatomical condition.

The device is intended for exclusive use by qualified medical personnel trained in the bridging of partial auditory ossicle defects.

2.10 Industry Standards: [807.92 (d)]

KURZ certifies compliance with required ISO/EN/ASTM/ AAMI/ANSI and other device-related standards that apply to the manufacture, packaging, labeling, sterilization, and reprocessing (custom instruments) of subject devices including the validation of these processes.

2.11 MRI Environment: [807.92 (d)]

Testing in a 0.5 Tesla nuclear magnetic resonance (NMR) 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. KURZ recommends strict adherence to the instructions for the use of magnetic resonance imaging tomographs.

2.12 Information Bearing on the Safety and Effectiveness: [807.92 (b)(3)]

The KURZ Angular Piston - Titanium Stapedial Prostheses have the same intended use as the previously cleared devices made of pure gold with titanium clamps. With the exception of the described material and changes in device length, there are no additional characteristics known that should adversely affect the safety and effectiveness of these implants.

The results of design validation raise no new issues of safety and effectiveness.

2.13 KURZ Angular Piston - Titanium Stapedial Prosthesis

COMPARISON of DESIGN + SAFETY and EFFECTIVENESS

Device	Titanium Angular Piston	Gold/Titanium Angular Piston
Catalog #	1006 600 – 602 0.4 mm Ø 1006 650 – 652 0.6 mm Ø	1005 600 0.4 mm Ø 1005 602 0.6 mm Ø
Intended Use	Bridging the stapes in case of otosclerosis: specifically for surgical revision in patients with a shortened incudal process, but also for primary surgery in patients with this anatomical condition	**Identical**
Model #	6	2
Dimensions **- Length** **Long Piston Stem** **Short End** **- Clamps**	 4.25 – 4.75 mm (0.25 mm intervals) 2.00 mm + Piston Ø 1.3 mm in open position	 6.00 mm 2.00 mm + Piston Ø 1.3 mm in open position
- Piston Ø	0.4 mm + 0.6 mm	**Identical**
Material	ASTM F67 Titanium	Pure Gold Piston Stem + 90° Handle ASTM F67 Titanium Clamps
Weight	Ø 0.4 mm = 5 – 7 mg Ø 0.6 mm = 9 – 11 mg	Ø 0.4 mm = 21 mg Ø 0.6 mm = 45 mg
Single Use	Yes	Yes
Sterile	Yes	Yes
Design Comparison	Smoothly rounded piston stem with 90° handle at upper end (2.0 mm long) holding two rounded band clamps whose open ends are slightly staggered so that they do not touch after closing around stump of incudal process. (Piston Ø = 0.4 + 0.6 mm)	**Identical**
Safety & Effectiveness of Material Change [807.92 (b)(1)]	Titanium is a clinically well-established implant material with excellent biocompatability. The much lighter weight appears to be better suited for implantation in the middle ear. Clinical evidence suggests that titanium has excellent sound conduction properties resulting in improved hearing gain. *Careful attention is to be paid to KURZ instructions.*	
Custom Accessory	KURZ Measuring Rod, Cat. # 8000 106	**Identical**

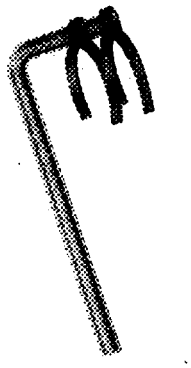
Signature  Date February 1, 2001

Uwe Steinhardt
Technical Director

3.1 Proposed Operating Guidelines

Heinz Kurz GmbH Medizintechnik **Special 510(k): Device Modification – 77 ETB**

Product:	**ANGULAR PISTON – TITANIUM**	
Description	Middle Ear Implant for Stapedioplasty	
Type	Stapedectomy or Stapedotomy Prosthesis	
Material	**Titanium (ASTM F 67 Medical Grade)**	
Author	Prof. Dr. K. Jahnke: Operation Guidelines	
Indication	***For bridging the stapes in case of otosclerosis; specifically for surgical revision in patients with a shortened incudal process, but also in primary surgery with this anatomical condition***	
Special Instrument Recommended	K 8000 106	KURZ Measuring Rod to Determine Appropriate Piston Length



Sizes + Catalog #'s	Ø **0.4 mm:** #1006 600: **4.25 mm** #1006 601: **4.50 mm** #1006 602: **4.75 mm** Ø **0.6 mm:** #1006 650: **4.25 mm** #1006 651: **4.50 mm** #1006 652: **4.75 mm**
Description of Implant and Intended Situs	The all-titanium prothesis consists of a round piston stem with a 90° handle, 2.40-2.60 mm in length, which carries two round band clamps. Their open ends are slightly staggered to prevent them from touching when closed. The clamps are designed to hold the stump of the long incudal process and serve to keep the prosthesis securely positioned. The piston enters the opened perilymphatic space through the stapes footplate.
Adjustment	• Close the clamps around the stump of the incudal process with McGee Wire Crimper
MRI	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 through MRI (NMR) has come to the attention of the manufacturer.
Surgical Procedure	**1. Primary Surgery** <u>Preparation:</u> Normal stapedectomy, partial stapedectomy or stapedotomy (resection, partial resection or perforation of the footplate and section of the stapedius tendon and of the incus-stapes joint as well as removal of the stapes crura above the footplate). While the inner ear is still closed (depending on the method of operation): Using the KURZ Measuring Rod (Cat. # 8000 106), select the appropriate prosthesis (3 lengths from 4.25 to 4.75 mm) by measuring the distance between the medial line of the incudal process and the still present footplate; add to this measurement the thickness of the footplate plus another 0.5 mm (approx.) to allow the piston to enter the vestibulum. <u>Implantation:</u> 1. Position the clamps around the stump of the incudal process and 2. Allow the base of the piston stem to enter the open vestibulum; 3. Close the two (2) clamps around the stump of the incudal process with McGee Wire Crimpers; 4. Coat the piston with one or more connective tissue flaps to avoid perilymphatic fistula.

	Surgical Revision 1. Carefully free the old prosthesis from surrounding bridles; 2. If necessary, open the old prosthesis at the loop around the incudal process and gently withdraw it, or dissect the connective tissue structures to free the device. 3. Determine the required piston length of the new prosthesis by measuring the length of the old one outside the operational field. 4. Follow implantation steps under 1.
Attention	Make sure that no foreign material, such as cotton fibers, is attached to the connective tissue flaps. The manufacturer urgently recommends use of fiber-free instrument cloths and synthetic microscope and patient drapes.
Aftercare	Aftercare according to normal procedure in middle ear surgery.
Additional Information	See Package Insert

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2001

Mr. Dagmar S. Mäser
FDA Liaison for Heinz Kurz GmbH Medizintechnik
Business Support International
Amstel 320-I
1017 AP Amsterdam
The Netherlands

Re: K010442
Trade Name: Angular Piston - Titanium Stapedial Prosthesis
Regulatory Class: II
Product Code: 77 ETB
Dated: February 12, 2001
Received: February 14, 2001

Dear Mr. Mäser:

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 requirements, 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) 594-6413. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

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

510(k) Number K010442

Device Name **Angular Piston - Titanium**

INDICATION FOR USE

For bridging the stapes in case of otosclerosis; specifically for surgical revision in patients with a shortened incudal process, but also in primary surgery with this anatomical condition.

Description of Implant and Intended Situs

The all-titanium prosthesis consists of a round piston stem with a 90° handle, 2 mm in length, which carries two (2) round band clamps. Their open ends are slightly staggered so that they do not touch when closed.

The clamps are designed to hold the stump of the long incudal process and serve to keep the prosthesis securely positioned. The piston enters the opened perilymphatic space through the stapes footplate.

(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 Use _____

(Per CFR 801 109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010442