NOV 0 9 2001

K 013573

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

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2. 510(k) SUMMARY of Safety and Effectiveness

As required by Section 807.92(c)

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

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Germany

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

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

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Fax +31-20-428 94 29
eMail bsi@xs4all.nl

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

October 10, 2001

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

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

2.5 Reason for Submission:

Change in material and design when compared to previously cleared device

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

K 972492 Bell Prosthesis (Partial)
Cleared 08/04/97

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

The all-titanium prosthesis consists of a clip with seven (7) resilient prongs, a shaft, and a head plate.

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

Material:

1. Titanium provides excellent sound conduction even at higher frequencies
2. Due to the lower specific weight of titanium, the device is substantially lighter than the gold KURZ Bell "Dresden" prosthesis

Design:

By pushing the elastic clip over the stapes head and upper part of the stapes, a more secure connection is established that not only eliminates the need for device manipulation in situ but also the chance of implant dislocation with a high degree of certainty.

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

Ossicle replacement in case of interrupted sound conducting chain in patients with intact, mobile stapes

2.10 Industry Standards: [807.92 (d)]

KURZ certifies compliance with all appropriate industry standards and the validation of methods and processes covered by these standards.

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.

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

The KURZ Clip Partial Prosthesis – Titanium "Dresden" has the same intended use as the previously cleared device made of pure gold. With the exception of the described material and design changes, 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.

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Geschäftsführer:
Heinz Kurz
Traute Kurz-Butzki
USt.-Id. Nr. DE 8115
[redacted]
Amtsgericht Tübinge

2.13 COMPARISON of DESIGN + SAFETY and EFFECTIVENESS

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	Titanium	Gold
Device	Clip Partial Prosthesis "Dresden"	Dresden Bell Prosthesis
Catalog #	1002 250 – 257	1001 023 – 030
Intended Use	Ossicle replacement in case of interrupted sound conducting chain in patients with intact, mobile stapes	**Identical**
# of Sizes	8	**Identical**
Dimensions - **Length** - **Head Plate Ø** - **Shaft Ø**	1.75 – 3.5 mm (0.25 mm intervals) 2.6 mm 0.2 mm	**Identical**
Material	ASTM F67 Titanium	Pure Gold
Weight	4-5 mg	10-12 mg
Single Use	Yes	**Identical**
Sterile	Yes	**Identical**
Design Comparison	Clip with seven (7) resilient prongs securely clips around stapes head and upper part of stapes. No manipulation and/or adjustment in situ.	The four (4) gold strips of Bell prosthesis are gently pushed against stapes with wire crimper to achieve mechanically close fit.
Custom Accessories	KURZ Sizer Cat.# 8000 121 KURZ Precise Cat # 8000 101	**Identical**
Safety & Effectiveness of Material and Design Changes [807.92 (b)(1)]	Titanium is a clinically well-established implant material with excellent biocompatibility. 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. The tensile clip mechanism significantly reduces the risk of implant implant dislocation while the secure but vibrant connection to the stapes head is expected to improve long-term hearing gains with appropriate physiological conditions. *Careful attention must be paid to KURZ operating guidelines*	

Signature _____ Date October 22, 2001

Uwe Steinhardt
Technical Director

Heinz Kurz GmbH
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2001

Heinz Kurz GmbH Medizintechnik
c/o Dagmar S. Mäser
Business Support International
Amstel 320-I
1017 AP Amsterdan
The Netherlands

Re: K013573
Trade/Device Name: Clip Partial Prosthesis-Titanium Dresden, Model 1002
Regulation Number: 21 CFR 874.3450
Regulation Name: Partial Ossicular Replacement Prosthesis
Regulatory Class: Class II
Product Code: ETB
Dated: October 24, 2001
Received: October 29, 2001

Dear Ms. 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 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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 K013573

Device Name **Clip Partial Prosthesis – Titanium "Dresden"**

NOV 0 9 2001

INDICATION FOR USE

Ossicle replacement in case of interrupted sound conducting chain in patients with intact, mobile stapes.

Description of Implant and Intended Situs

The prosthesis consists of a clip consisting of seven (7) resilient prongs, a shaft, and a head plate.

Holding the device vertically to the stapes axis, the clip is gently pushed over the stapes head so that the titanium prongs with their built-in tension securely grasp the stapes head and upper part of the stapes and the two somewhat shorter rear prongs are positioned on either side of the stapedial tendon. The head plate is covered with a thinned cartilage slice and placed under the manubrium mallei or under the tympanic membrane.

(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 K013573