3/31/99 K990923

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

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Medizintechnik
Hausanschrift:
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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)]

Heinz Kurz GmbH Medizintechnik
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usteinhardt@kurzmed.de

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

Dagmar S. Maeser
Business Support International
Amstel 320-I — Tel. +31-20-428 95 91
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The Netherlands — eMail bsi@xs4all.nl
bsi2@compuserve.com

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

March 10, 1999

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

Proprietary	
Partial	Tuebingen Titanium Prosthesis (TTP) BELL VARIO
Total	Tuebingen Titanium Prosthesis (TTP) AERIAL VARIO
Common	Length-Adjustable Partial (BELL) and Total (AERIAL) Ossicular Replacement Prostheses
Classification	
Partial	Middle Ear, Prosthesis, Partial Ossicular Replacement Prostheses (ETB, CFR 874.3450)
Total	Middle Ear, Prosthesis, Ossicular Replacement, Total (ETA, CFR 874.3490)

2.5 Reason for Submission:

Design change of previously cleared devices (s. 2.6, 2.7, 2.8, 2.12 and Comparison Table 2.13).

2.6 Design Change to Existing Devices: [807.92 (a)(3)]

K 972492 Bell Prosthesis (Partial), Tuebingen
K 972585 Aerial Prosthesis (Total), Tuebingen

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

KURZ Tuebingen Titanium Prostheses (TTP) BELL + AERIAL VARIO are length-variable sterile middle ear prostheses.

They are identical to the previously cleared devices with the following exceptions: Instead of eight (8) and fourteen (14) fixed-length sizes (Bell and Aerial respectively), the TTP VARIO models come in one size only. The head plate slides on the shaft and can be irreversibly attached at the exact length point required for the patient. The extra shaft length is cut off behind the head plate (s. Package Insert and Manufacturer's Instructions).

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

This modification does not affect the safety and effectiveness of the previously cleared devices, but has distinct advantages:

1. Precise fittings for the patient at 0.25 mm or less intervals;
2. The assurance that the right length prosthesis is on hand – for every patient – regardless of length required.
3. Health care cost reduction due to the need for smaller inventories.

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

BELL VARIO	Partial ossicle replacement in case of interrupted sound conducting chain and intact mobile stapes.
AERIAL VARIO	Total ossicle replacement in case of interrupted sound conducting chain and intact mobile stapes between tympanic membrane and stapes foot plate.

Both devices are only intended for use by qualified medical personnel trained in the bridging of partial or complete 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 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.

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

The KURZ Tuebingen Titanium Prostheses (TTP) BELL and AERIAL VARIO have the same intended use as the previously cleared devices. With the exception of the described design change, 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 Tuebingen Titanium Prostheses (TTP) VARIO BELL + AERIAL

D E S I G N + SAFETY and EFFECTIVENESS C O M P A R I S O N

Device	Bell VARIO	Bell	Aerial VARIO	Aerial
Catalog #	1002 010	10022xx	1004 010	10042xx
Intended Use	Partial Ossicle Replacement in case of interrupted sound conducting chain and intact stapes	Partial Ossicle Replacement in case of interrupted sound conducting chain and intact stapes	Total Ossicle Replacement in case of interrupted sound conducting chain and intact stapes	Total Ossicle Replacement in case of interrupted sound conducting chain and intact stapes

Model # **Dimensions**	1 – 1.75 – 4.5 mm	8 – 1.75 – 3.5 mm @ 0.25 mm intervals	1 – 3.0 – 7.0 mm	14 – 3.0 – 7.00 mm @ 0.25 mm intervals
- Shaft Ø	0.2 mm	0.2 mm	0.2 mm	0.2 mm
- Head Plate	2.6 x 3.6 x 0.22 mm	2.6 x 3.6 x 0.22 mm	2.6 x 3.6 x 0.22 mm	2.6 x 3.6 x 0.22 mm
Material	ASTM F67 Titanium	ASTM F 67 Titanium	ASTM F67 Titanium	ASTM F67 Titanium
Single Use Reusable	Single Use	Single Use	Single Use	Single Use
Sterile	Yes	Yes	Yes	Yes
Design Comparison	The identical head plate glides on the identical Ø shaft to the exact length required for the patient and is then irreversibly connected. The extra shaft length is cut off.	8 common lengths at 0.25 mm intervals. The head plate is permanently attached to prosthesis shaft.	The identical head plate glides on the identical Ø shaft to the exact length required for the patient and is then irreversibly connected. The extra shaft length is cut off.	14 common lengths at 0.25 mm intervals. The head plate is permanently attached to the prosthesis shaft.
Safety & Effectiveness of Design Change [807.92 (b)(1)]	Tensile strength tests at approx. seven times the middle ear forces acting on the implant have proven the stability of the connection. The implant is as safe and effective as the previously cleared Tuebingen Bell Partial Prosthesis. *Careful attention is to be paid to KURZ instructions.*		Tensile strength tests at approx. seven times the middle ear forces acting on the implant have proven the stability of the connection. The implant is as safe and effective as the previously cleared Tuebingen Aerial Total Prosthesis. *Careful attention is to be paid to KURZ instructions.*	
Additional Required Accessory	VARIO Holder		VARIO Holder	

Signature _____ Date March 11, 1999

Dagmar S. Maeser
FDA Liaison for KURZ

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 1999

Dagmar S. Maeser
FDA Liasion for Heinz Kurz GmbH Medizintechnik
Amstel 320-I
1017 AP Amsterdam
Netherlands

Re: K990923
Trade Name: Partial/Total Length-Variable Titanuim Middle Ear Prostheses
Regulatory Class: II
Product Code: 77 ETB and 77 ETA
Dated: February 3, 1999
Received: February 4, 1999

Dear Mr. 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 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) 594-4613. 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Heinz Kurz GmbH Medizintechnik SPECIAL 510(k) – 77 ETA

510(k) Number K990923

Device Name **Tuebingen Titanium Prosthesis (TTP) AERIAL VARIO**

INDICATIONS FOR USE

Ossicle replacement in case of interrupted sound conducting chain and intact mobile stapes between the tympanic membrane and the stapes foot plate.

The Tuebingen Titanium Prosthesis (TIP) AERIAL VARIO is intended for bridging a complete auditory ossicle defect.

Description of Implant and Intended Situs

The prosthesis consists of a cup, a shaft and a head plate. The correct length must be measured and the prosthesis adjusted accordingly (see manufacturer's instructions for measuring and adjusting the correct length!). Then the cup is placed centrally on the foot plate. After regular implantation the head plate is under the manubrium mallei, the tympanic membrane or another tympanic cover, and is covered laterally (between head plate and tympanic membrane) with a thin slice of cartilage or a cartilage-perichondrium transplant.

(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)

VI

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990923

(for HPS)

Heinz Kurz GmbH Medizintechnik SPECIAL 510(k) – 77 ETB

510(k) Number K990923

Device Name **Tuebingen Titanium Prosthesis (TTP) BELL VARIO**

INDICATIONS FOR USE

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

The Tuebingen Titanium Prosthesis (TIP) BELL VARIO is intended for partial replacement of the auditory ossicles.

Description of Implant and Intended Situs

The prosthesis consists of a slit bell, a shaft and a head plate. The correct length must be measured and the prosthesis adjusted accordingly (see manufacturer's instructions for measuring and adjusting the correct length!). Then the bell is placed centrally on the stapes head or – if it no longer exists – on the still complete stapes arch. After regular implantation the head plate is under the manubrium mallei, the tympanic membrane, or another tympanic cover, and is covered laterally (between head plate and tympanic membrane) with a thin slice of cartilage or a cartilage-perichondrium transplant.

(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)

V

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990923

Karen Baker (for HPS)