



FEB 8 2013

## 510(k) SUMMARY of Safety and Effectiveness

As required by CFR Section 807.92(c)

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

Heinz Kurz GmbH Medizintechnik  
Tübingen Str. 3  
D-72144 Dusslingen  
Germany  
Tel. +49-7072-91 79 0  
Fax +49-7072-91 79 79  
Email [info@kurzmed.de](mailto:info@kurzmed.de)

**2. Submission Correspondent** [807.92 (a)(1)]

Dagmar Mäser  
Business Support International V.O.F.  
Amstel 320-I  
1017 AP Amsterdam  
The Netherlands<sup>1</sup>  
Tel. +31-20-428 95 91  
Tel. + 1-828-622-7572  
Fax +31-20-201-0175  
Email [bsi@xs4all.nl](mailto:bsi@xs4all.nl)

**3. Date Summary Prepared** [807.92 (a)(1)]

February 4, 2012

**4. Reason for Submission** [807.92(3)(i)]

New Device

**5. Device Names** [807.92 (a)(2)]

<b>Proprietary</b>	NiTiBOND Stapes Prosthesis
<b>Common</b>	Stapes Prosthesis, Stapes Piston
<b>Classification</b>	Prosthesis, Partial Ossicular Replacement
<b>Product Code</b>	77 ETB
<b>Regulation #</b>	CFR 874.3450

**6. Predicate Devices** [807.92(a)(3)]

K003214	Smart Piston	- GYRUS ENT L.L.C
K063374	Eclipse Nitinol Locking Piston	- GRACE MEDICAL, INC
K021479	Clip® Piston áWengen	- HEINZ KURZ GMBH

<sup>1</sup> NC Address: BSI, 271 Waldroup Road, PO Box 457, Hot Springs, NC 28743



## 7. Device Description [807.92(a)(4)]

The stapes prosthesis consists of a Nitinol loop and the standard KURZ shaft made of pure titanium (ASTM F67).

The flat loop band diffuses the impact of pressure on the incus. When applying heat to the ContactFree Zones, the shape memory features of Nitinol cause the loop to close. The ContactFree Zones serve as heat blockers, limit heat dispersion on the mucosa and minimize the risk of incus strangulation. The prosthesis comes with an accessory, the Thermo-Dummy®, to predetermine the lowest laser setting that will close the prosthesis loop outside the patient's ear before inserting the implant.

## 8. Statement of Intended Use [807.92(a)(5)]

The prosthesis is intended for ossicular replacement to restore functionality to the middle ear in cases of pathological changes of the sound transmission system. The NiTiBOND Stapes Prosthesis acts as a bridge between the long process of the incus and the base of the stapes, with the piston extending into the perilymphatic space of the inner ear.

The prosthesis consists of a nickel-titanium alloy (Nitinol) loop and a pure titanium piston (ASTM F67).

Specifically, the device is designed for the treatment of

- (1) Otosclerosis (stapedial fixation) / congenital stapedial fixation
- (2) Traumatic injury to the ossicular chain
- (3) Malformation of the middle ear
- (4) Revision surgery to correct inadequate hearing improvement, e.g. through dislocation of a prosthesis

## 9. Performance Data [807.92(b)]

### (i) Non-Clinical Performance Tests [807.92(b)(1)]

The performance specifications were met. The following tests were conducted:





- Coupling Effectiveness
- Stability of Coupling during Sound Transmission
- MRI Environment
- Biocompatibility
- Shelf Life Testing
- Sterilization Validation
- Packaging Validation

### (ii) Clinical Evaluation [807.92(b)(2)]

According to published literature, post-operative hearing improvement is substantially equivalent when compared to legally marketed SE devices.



**10. Comparison with Predicate Devices [807.92(a)(6)]**

Device	<b>NiTiBOND Stapes Prosthesis</b> Heinz KURZ GmbH <b>K112616</b>	<b>SMart Piston</b> GYRUS ACMI – Olympus <b>K003214</b>	<b>Eclipse Nitinol Piston</b> GRACE Medical Inc. <b>K063374</b>	<b>Clip® Piston</b> âWengen Heinz KURZ GmbH <b>K021479</b>
<b>Design Comparison</b>				
<b>Intended Use</b>	The prosthesis is intended for ossicular replacement to restore functionality to the middle ear in cases of pathological changes of the sound transmission system.	Identical	Identical	Identical
<b>Method of Attachment</b>	Heat Application	Heat Application	Heat Application	Manual
<b># of Sizes</b>	16 (8 for each Ø)	15 (5 for each Ø)	12 (6 for each Ø)	16 (8 for each Ø)
<b>Dimensions Length [mm]</b>	3.5 – 5.5 (0.25 mm intervals)	3.75 – 4.75 (0.25 mm intervals)	3.75 – 5.0 (0.25 mm intervals)	3.5 – 5.5 (0.25 mm intervals)
<b>Piston Ø [mm]</b>	0.4 / 0.6	0.5 / 0.6 / 0.8	0.5 / 0.6	0.4 / 0.6
<b>Width of Loop Band [mm]</b>	0.25	Wire	Wire	0.25
<b>Materials Loop Piston</b>	Nitinol Titanium (ASTM F67)	Nitinol Fluoroplastic	Nitinol Fluoroplastic	Titanium (ASTM F67) Titanium (ASTM F67)
<b>Single Use</b>	Yes	Yes	Yes	Yes
<b>Sterile</b>	Yes	Yes	Yes	Yes
<b>MRI</b>	MR Conditional 1.5, 3 + 7 Tesla	MR Conditional 3 Tesla or less	MR Conditional 3 Tesla or less	MR Conditional 1.5, 3 + 7 Tesla
<b>Biocompatible</b>	Yes	Yes	Yes	Yes
<b>Accessory</b>	Thermo-Dummy® to determine laser setting for closing the loop outside the patient's ear prior to implant insertion	No	No	Not Applicable



## 11. Information Bearing on Device Safety and Effectiveness

[807.92 (b)(3)]

The differences between the KURZ NiTiBOND Stapes Prosthesis and the predicate devices are designed to enhance the safety and effectiveness of stapedotomy procedures.

Nonclinical and clinical testing demonstrate that the KURZ NiTiBOND is as safe and effective as the predicate devices.

There are no known characteristics that would introduce adverse effects.

**The results of non-clinical and clinical design and performance validations raise no new issues of safety and effectiveness.**



February 8, 2013

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Heinz Kurz GmbH Medizintechnik  
% Ms. Kristina Bitzer  
Manager Regulatory Affairs  
Maeser Support International, V.O.F.  
Amstel 320-1  
Amsterdam  
Neitherlands

Re: K112616

Trade/Device Name: NitiBond Stapes Prosthesis  
Regulation Number: 21 CFR 874.3450  
Regulation Name: Partial Ossicular Replacement Prosthesis  
Regulatory Class: Class II  
Product Code: ETB  
Dated: January 28, 2013  
Received: February 6, 2013

Dear Ms. Bitzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21; Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Eric A. Mann** for

Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic and Ear, Nose,  
and Throat Devices  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K112616

Device Name: NiTiBOND Stapes Prosthesis

### Indications for Use:

The prostheses are intended for partial ossicular replacement to restore functionality to the middle ear in cases of pathological changes of the sound transmission system. The NiTiBOND Stapes Prosthesis act as a bridge between the long process of the incus and the base of the stapes, with the piston extending into the perilymphatic space of the inner ear.

The loop consists of a nickel-titanium alloy (Nitinol), while the piston is made of pure titanium.

Specifically, the devices are designed for the treatment of

1. Otosclerosis (stapedial fixation) / congenital stapedial fixation
2. Traumatic injury to the ossicular chain
3. Malformation of the middle ear
4. Revision surgery to correct inadequate hearing improvement, e.g. through dislocation of a prosthesis

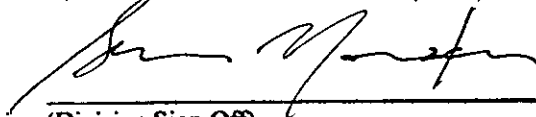
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Prescription Use   X    
(Per 21 CFR 801.109)

(Division Sign-Off)  
Division of Ophthalmic and Ear, Nose  
and Throat Devices  
510(k) Number   K112616