SEP 16 1999

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510(K) – 77 ETB

K992839

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2. 510(k) SUMMARY
of Safety and Effectiveness
+
SE Comparison Table

Heinz Kurz GmbH Medizintechnik
As required by Section 807.92

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)]
August 18, 1999

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

Proprietary	Socket Stapes Piston w/o Loop (Schobel) + (Schobel-Causse)
Common	Partial Ossicular Replacement Prosthesis, Stapes Piston
Classification	Middle Ear, Prosthesis, Partial Ossicular Replacement

Geschäftsführer:
Heinz Kurz
Traute Kurz-Butzki
USt.-Id. Nr. DE 811570328

Volksbank Steinlach-Wiesaz eG
(BLZ 640 618 54) Konto-Nr. 70 150 001

Baden-Württembergische Bank Tübingen
(BLZ 641 200 30) Konto-Nr. 120 140 2300

Amtsgericht Tübingen
HRB 1424

2.5 Reason for Submission: [807.81(2)]

New Device

2.6 Predicate Devices [807.92(a)(3)]

Manufacturer			
Smith & Nephew Richards		XOMED	
Proprietary Names	K[1] Catalog #'s		K[2] Catalog #'s
Fluoroplastic Pistons	14-0xxx	Causse TEF Piston - PTFE Polymer	11-563xx
Cup Pistons - Stainless Steel	14-2xxx	Causse TEF Piston Large Loop - Teflon	11-290xx
Lippy Modified Stapes Prosth. - Stainless Steel	14-211x	Robinson - Teflon	XO-240x
Richards Bucket Handle Prosth. - Stainless Steel	14-20xx	'Cupped Designs' - Stainless Steel	11-33xxx
- Fluoroplastic	14-21xx	Bailey/Pappas Modified - Stainless Steel	11-564xx
Shea Cup Pistons - Fluoropl. Left/Right Ear	14-04xx		
Shea Platinum/Fluoropl.	14-06xx		

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

Funnel-shaped titanium stapes prosthesis (piston) which is articulated to the lenticular process of the long limb of the incus. Thus, neither a loop nor a frame are necessary for linking the prosthesis.

The Schobel-Causse model is equipped with a process perpendicular to the piston stem. The stapedius reflex is reconstructed by latching the stapedius tendon into the u-shaped process end. (indicated for first-time procedures).

The shaft of both prosthesis models (Schobel + Schobel-Causse) is placed on the membrane (vein or fascia) in the oval window. With this technique, the graft interposition serves as a replacement of the annular ligament, discourages the piston shaft from pressing into the saccule, and effectively inhibits the development of possible perilymphatic fistula.

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

Like the SE devices, the KURZ stapes prostheses, Models Schobel + Schobel-Causse, are designed for replacement of the stapes after stapedotomy or stapedectomy in otosclerosis surgery.

Model Schobel-Causse is indicated for first-time procedures only (placement of stapedius tendon in U-shaped hook), while Model Schobel can also be used in secondary surgery. [3]

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[1] It could not be determined, which (or if any) of the following submissions cleared SE devices for commercial distribution or if they fall under the preamendment ruling:
K910685, K925443, K950885, K950886, K950887, K950984, K952481

[2] It could not be determined if K872112 or K964909 contain SE devices or if they are possibly pre-amendment.

[3] As late as 10-15 years after initial procedures, secondary surgery is sometimes indicated after implanting of

2.9 Difference in Design and Technological Characteristics when Compared to SE Devices [807.92 (a)(6)]

The KURZ Stapes Cup Pistons are manufactured exclusively of high-grade surgical titanium while the various models of SE devices are made of fluoroplastic, stainless steel and a combination of fluoroplastic and titanium.

The design is very similar. Both KURZ and SE devices consist of a straight stem, the piston, topped by a sort of cup (S+N, Xomed) or funnel-shaped socket (KURZ). The major difference lies in SE devices requiring a loop for fastening to the incus process while the KURZ pistons are articulated.

The piston diameter for KURZ devices is 0.4 mm and in SE devices ranges from 0.3 mm to 0.8 mm.

2.10 Discussion of Safety and Effectiveness [807.92(b)]

Clinical results[4] to date have shown that KURZ titanium middle-ear implants compare favorably with SE devices regarding safety and effectiveness. The Schobel/Schobel-Causse implants exhibit the following features:

2.10.1 Implant Length

KURZ implants are 3.5 – 4.5 mm long and come in 0.25 mm increments while the length of SE devices ranges from 4.0 – 6.0 (Xomed) and 3.5 – 6.0 (S&N) and – with some exceptions - usually are in 0.5 mm steps.
Benefit: *Very precise fitting*

2.10.2 Fixation to Incus without Loop

The design corresponds with the anatomic structure of the ossicular chain. The socket-like piston top is articulated with the incus, eliminating the need for a wire loop or frame to assure fixation as is common with SE devices.
Benefit: *Eliminates loosening of loop (SE devices) with resulting hearing loss and associated risks due to pressure at the incudal process such as atrophy, necrosis, detachment of incudal process).* (s. Footnote 1)

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[3] As late as 10-15 years after initial procedures, secondary surgery is sometimes indicated after implanting of conventional pistons. The loop used for fastening the piston around the incudal process may cause atrophy of the bone which results in the implant coming loose. This may cause intermittent hearing problems depending on the ear pressure in the middle ear.

[4] See Exhibit 2 for Intermediate Report on clinical investigation on titanium middle-ear implants in comparison to other materials.

2.10.3 Drastic Reduction of Perilymphatic Fistula or Necrosis Formation

If the surgeon follows the prescribed surgical technique, the formation of perilymphatic fistula or necrosis due to pressure at the incudal process can be avoided with high degree of certainty.

2.10.4 Substitution of Stapedial Annular Ligament (Schobel + Schobel-Causse)

Through placement of vein or fascia over vestibule. This is also practiced with SE device, Causse TEF from XOMED.

2.10.5 Maintenance of Stapedius Reflex Function (Schobel-Causse)

Although the method of attachment to the piston varies, like the Causse TEF piston from XOMED, the stapedius tendon is retained to preserve the stapedial muscle reflex:

Benefits:
1. Protection of inner ear from acoustic trauma;
2. Improvement of patients' hearing in noisy environment;
3. Patients can hear own voice more normally;
4. Improvement of noise localization;
5. Regulation of inner ear pressure

2.10.6 Biocompatibility

ASTM F67 medical grade titanium has a proven record of excellent biocompatibility.

2.10.7 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 adverse effects has come to the attention of the manufacturer.

2.10.8 Long-Term Clinical Results

Since I979 the Schobel socket piston (without loop) design has been implanted with excellent hearing improvement and not a single case of incus necrosis, loosening of articulation with lenticular processus, or membrane penetration into the vestibulum. Until I996, the piston material consisted of MACOR, a biocompatible glass ceramic product manufactured by RICHARDS. Since then, KURZ titanium prostheses have been used exclusively (see Exh. 3: Prof. H. Schobel, *On Development of New Stapes Prosthesis in Otosclerosis Surgery)*

2.10.9 Hearing Parameters

At least equal, if not better improvement of all hearing parameters can be achieved when compared to SE devices

2.11 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, and sterilization,of subject devices including the validation of these processes.

2.12 Information Bearing on the Safety and Effectiveness:

[807.92 (b)(3)]

The KURZ titanium loop-less socket piston has the same intended use as predicate devices. The different material (*titanium*) and design modification (*socket top – no loop*) do not adversely affect the safety and effectiveness of these implants, but rather enhance biocompatibility, implant stability and long-term problem-free fixation, and audio results achieved.

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

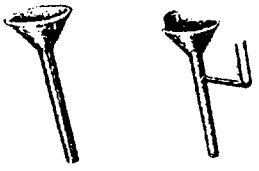
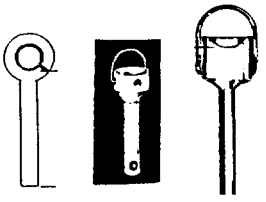
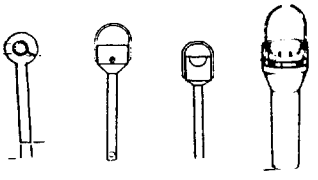
2.13 COMPARISON WITH PREDICATE DEVICES

	KURZ	XOMED	SMITH + NEPHEW

2.13 COMPARISON WITH PREDICATE DEVICES

	KURZ	XOMED	SMITH & NEPHEW
Device	**Socket Stapes Piston w/o Loop**	**1. Causse TEF-Pistons** **2. Robinson Stapedectomy** **3. Cupped Pistons**	**1. Fluoroplastic Pistons** **2. Cup Pistons** **3. Lippy Modified – Stainless** **4. Richards Bucket Handle** **5. Shea Cup** **6. Shea Platinum/Fluoroplastic**
Model(s)	1. Schobel 100650x 2. Schobel-Causse 100651x	1. PTFE Polymer 11-563xx Teflon 11-290xx 2. Teflon XO-24xx 3. Stainless St. 11-33xxx 11-564xx	1. Fluoroplastic 14-0xxx 2. Stainless 14-2xxx 3. Stainless 14-211x 4. Stainless 14-20xx Fluoroplastic 14-21xx 5. Fluoropl. L/R 14-04xx 5. Fluoroplastic w/ Platinum Loop 14-06xx
Intended Use **Schobel** **Schobel-Causse**	Otosclerosis Surgery: Replacement of Stapes after Stapedectomy and Stapedotomy initial & secondary surgery initial; designed to receive stapedius tendon to retain stapedial muscle reflex	Otosclerosis Surgery: Replacement of Stapes after Stapedectomy and Stapedotomy Causse TEF Pistons: Retention of stapedial tendon	Otosclerosis Surgery: Replacement of Stapes after Stapedectomy
Material	ASTM F67 Medical Grade Titanium	PTFE Polymer Teflon Stainless Steel	Fluoroplastic, Stainless Steel, Fluoroplastic with Platinum Loop
Contra-Indications	Known titanium allergy + general preoperative considerations, i.e.: - acute & chronic infections - general wound healing disorders - alcohol, drugs, and nicotine abuse	Not known	1. When more conservative treatment will suffice; 2. When infection is present as later scarring could cause displacement of prosthesis; 3. Stapedectomy in better or only-hearing ear not advisable due to risk of cochlear deafness.
Adverse Effects + Interactions **MRI** **X-ray + Computed Tomography** **Microwave**	• Harmless; The image quality may be impeded near implant • Piston can be precisely localized • DO NOT EXPOSE (s. WARNINGS below)	Not known	Complications include: 1. Postoperative sensorineural deafness due to surgical trauma and reparative granuloma and perilymph fistula; 2. Labyrinthitis; 3. Vertigo; 4. Incus necrosis; 5. Tympanic membrane perfor' 6. Otitis media; 7. Prosthesis displacement; 8. Recurrence of oval window fixation.
Single Use Device	YES	YES	YES
Provided Sterile	YES	YES	YES
Sterilization Method	Gamma Irradiation	Not known	Ethylene Oxide

2.13 COMPARISON WITH PREDICATE DEVICES

	KURZ	XOMED	SMITH + NEPHEW
Resterilization Permitted	NO	Not known	YES – ETO, Autoclaving (250-254° F) and Flash Steam Autoclave (270-274° F) depending on implant material
Design Comparison Description	Titanium piston (Ø 0.4mm) with socket-like top for articulation to lenticular incus process.	Piston with cup and wire loop for fastening around incus process 'Cupped Piston Design' displays a notch in cup to 'cradle' incus arm.	Fluoroplastic and stainless steel piston (Ø 0.4 – 0.8 mm) with cup-like top and loop for fastening implant around incudal process.
Schobel-Causse	0.7 mm beneath socket base, thin peg, 0.7 mm long, projects perpendicular to shaft. Its U-shaped ending holds stapedius tendon. Socket pan has raised lip on opposite side to prevent luxation of piston head with strong stapedius reflex.		
Design Comparison Illustration (Not shown at same scale)	 *Schobel* *Schobel-Causse*	 Causse *Robinson* Cupped	 Fluoropl. Classic Richard B. Shea
Dimensions (mm) - **Lengths**	4.0 – 4.5 (0.25 mm increments) Standard Length: 4.25 mm	**Type Ø Lengths** CausseTEF 0.3 4.5 – 6.0 0.6 4.0 – 6.0 0.7 4.0 – 5.0 Robinson 0.6 4.0 – 4.5 Cupped P. 0.4 4.0 – 5.0 0.6 4.0 – 4. 5	**Type Ø Lengths** Fluoroplastic 0.6 3.5 – 6.0 0.8 4.0 – 6.0 Classic Stapes 0.4 4.0 – 5.0 0.6 4.0 – 5.0 Lippy Modif'd 0.4 3.65 - 5.1 Richard Bucket 0.4 3.5 – 5.0 0.6 3.5 – 5.0 Shea Cup 0.8 4.0 – 6.0 Shea Platinum/ Fluoroplastic 0.6 3.5 – 5.0 0.8 3.5 – 5.0
- **Piston Ø**	0.4 mm		
	Length in 0.25 mm increments	Bailey/Pappas Model in 0.25 mm increments	With exception of Platinum/Fluoro-Plastic (0.25 mm) in 0.5 mm increm
Weight [5] **Schobel** **Schobel-Causse**	3.5 mg 4.0 mg	Not labeled	Not labeled; known example: **Fluoplastic-Platinum Length 5 mm - Ø 6 mm =5 mg**
Handling Precautions	None	Not known	None labeled

[5] These are approx. weights. Although the implants vary in length from 4.0 – 4.5, the weight differences are neglible and so tiny that they are of no practical consequence to surgeon or patient.

2.13 COMPARISON WITH PREDICATE DEVICES

	KURZ	XOMED	SMITH & NEPHEW
Substitution of Stapedial Annular Ligament [6]	YES	YES – with Causse-TEF	YES
Retention of Stapedius Tendon[7]	YES – Only with Schobel-Causse Model in primary surgery	YES – with Causse-TEF	NO
Surgical Procedure	**Enaural, Endomeatal or Retroauricular:** - Atticotomy to expose ossicular chain; - Determine prosthesis length prior to interrupting chain; **Caution: Piston may not project more than 0.5 mm into vestibule!** - Cut incudostapedial joint without damaging incudal process; - Cut dorsal stapedial crus just above and below stapedius tendon attachment; - Keep flap of vein or fascia in standby position; - With laser or diamond drill cut 0.8 mm Ø hole in footplate; - Close immediately with vein or fascia; - While slightly lifting incudal process, place prosthesis on membrane and connect socket to incudal process. - Nest stapedius tendon with osseous fragment in U-shaped hooklet of Schobel-Causse prosthesis (see detailed surgical instructions available from U.S distributor and/or manufacturer)	**Causse TEF** 0.8mm hole is drilled in third posterior of footplate. Large vein graft interposition is used to discourage piston shaft from pressing upon saccule in case of vacuum in middle ear. Gently crimping the loop helps secure it around incus. Seal is made with small pieces of perivenous tissue to secure position. **Cupped Piston Design** Self-centering prostheses eliiminate need for wire crimping around incus.	Not available
Intended for Use in MRI Environment	Yes	Not labeled	Not labeled
Biocompatible	Yes	Yes	Yes
WARNINGS Microwave	Do not subject to microwave radiation	Not specified	Not specified
Custom Accessories	NONE	None specified	None specified

[6] Sealing of oval window with autogenous tissue (vein, fascia) to prevent perilymph fistula.

[7] For preservation of stapedial muscle reflex (s. also Exh. 3, pp 3+4; Exh. 6a: *Stapedius Tendon Reconstruction During Stapedotomy: Techniques and Results and Exh. 6b: Preservation of the Stapedius Tendon in Laser Stapes Surgery,* Laryngoscope 108; Oct. 1998)

Distinctive Features of *KURZ* Socket Stapes Pistons w/o Loop (Schobel + Schobel-Causse)

1. Pistons articulate with incus process. No loop required for fastening prosthesis on incudal process.

   Blood circulation in delicate periosteum is not inhibited; therefore, necrosis due to pressure at incudal process may be avoided with high degree of certainty.

2. Easy Placement: Positioning between fascia-covered oval window and incudal process under slight tension.
   - *No cutting or implant manipulation;*
   - *0.25 mm length increments assure exact fitting;*
   - *Substitution of stapedial annular ligament drastically reduces perilymphatic fistula formation.*

3. Special hook for easy connection of stapedius tendon. in primary surgery (Schobel-Causse)
   Maintenance of stapedius reflex function.

4. Excellent biocompatibility of titanium material.

5. No special instruments.

8/19/1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1999

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

Re: K992839
Trade Name: Socket Stapes Piston w/o Loop (Schobel) + (Schobel-Causse)
Regulatory Class: II
Product Code: 77 ETB
Dated: August 18, 1999
Received: August 23, 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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.

Sincerely yours,

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

Enclosure

510(k) Number K992839

Device Names
1 Socket Stapes Piston w/o Loop (Schobel)
2 Socket Stapes Piston w/o Loop (Schobel-Causse)

Classification Prosthesis, Partial Ossicular Replacement

Product Code 77 ETB **Class II** 21 CFR 874.3450

INDICATIONS FOR USE

Otosclerosis Surgery: Replacement of the stapes after stapedotomy and stapedectomy.

SCHOBEL: Initial and secondary surgery

SCHOBEL-CAUSSE: Initial surgery with retention of stapedial muscle reflex.

The stapes prostheses and custom accessories are exclusively intended for use by qualified medical personnel trained in middle ear reconstructive surgery.

(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)

(Division Sign-Off)
Division of Ophthalmic Devic...
510(k) Number K992839

(Optional Format 1-2-96)