K021479

MAY 21 2002

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

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

April 30, 2001

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

Proprietary	CliP Piston àWengen
Common	Stapedial Piston
Classification	Middle Ear Prosthesis, Partial Ossicular Replacement
Product Code	77 ETB
Regulation #	CFR 874.3450

2.5 Reason for Submission:

Change in design when compared to previously cleared device

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

K 002221 K-Piston Titanium Stapedial Prosthesis (Partial)
Cleared 08/09/2000

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

The all-titanium prosthesis consists of an undulated, self-retaining, two-limbed clip that is laser-welded to a conventional KURZ piston shaft.

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

1. To reduce risk of tissue necrosis by improving vascular circulation;
2. To standardize and significantly shorten surgical procedure by 'click-on' mechanism for attachment to long incudal process;
3. To eliminate need for instruments and crimping and to reduce potential risks connected therewith;
4. To improve audiological results by the unique attachment to incudal process

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

Bridging the stapes in cases of otosclerosis

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)]

Like the K-Piston Titanium Stapedial Prosthesis, the KURZ CliP àWengen is used for bridging the stapes in cases of otosclerosis. The click-on mechanism and the self-retaining design shorten the procedure, minimize the risks connected with instrument manipulation and, by improving vascular circulation, reduce the risk of tissue necrosis. The gentle attachment to the incudal process along the axis of mechanical sound transmission is expected to result in equal if not better audiological post-operative hearing gain. 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 COMPARISON of DESIGN + SAFETY and EFFECTIVENESS

Device	CliP àWengen	Titanium K-Piston K 002221
Catalog #	1006 805 – 1006 861	1006 103 – 1006 170
Intended Use	Bridging the stapes in cases of otosclerosis	1. Bridging the stapes in cases of otosclerosis 2. Bridging defects of the ossicular chain between manubrium mallei and vestibulum (malleovestibulopexy)
# of Sizes	12 (6 for each Ø)	28 (14 for each Ø)
Device Lengths	4.00 – 5.00 mm (0.25 mm intervals) 5.00 – 5.50 mm (0.50 mm interval)	3.50 – 6.00 mm (0.25 mm intervals) 6.00 – 10.00 mm (1.00 mm intervals
Piston Ø	0.4 + 0.6 mm	**Identical**
Material	ASTM F67 Titanium	**Identical**
Single Use	Yes	**Identical**
Sterile	Yes	**Identical**
Design Comparison	An open clip is attached to a 0.2 mm shaft that is seamlessly laserwelded to the piston stem (0.4 + 0.6 mm)	A laterally displaced band loop is attached to a 0.2 mm shaft that is seamlessly laserwelded to the piston stem (0.4 + 0.6 mm)
Custom Accessories	KURZ Measuring Rod Cat. # 8000 106 (to determine proper device length)	**Identical**
Safety & Effectiveness of Material and Design Changes [807.92 (b)(1)]	The tensile clip-on mechanism shortens surgical procedure, reduces risk of tissue necrosis on incudal process by improving vascular circulation, reduces risk of implant dislocation with high degree of certainty, and potentially improves long-term hearing gain with appropriate physiological conditions. Clinical test results to date confirm the safety and effectiveness of the new design. There are no known characteristics that would introduce adverse effects.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2002

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

Re: K021479
Trade/Device Name: CliP Piston à Wengen
Regulation Number: 21 CFR 874.3450
Regulation Name: Middle Ear Prosthesis, Partial Ossicular Replacement
Regulatory Class: Class II
Product Code: ETB
Dated: May 6, 2002
Received: May 8, 2002

Dear Ms. Mäser:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

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 K021479

Device Name **CliP Piston àWengen**

INDICATIONS FOR USE

For bridging the stapes in case of otosclerosis;

Description of Implant and Intended Situs

The titanium prosthesis consists of a piston with an open undulated clip at its end. Contrary to convential prostheses, the CliP requires no crimping. After positioning it on the long incudal process, slightly above the incudostapedial joint, it is permanently attached with a slight push of a microhook instrument. The CliP is self-retaining and stays securely in place due to the elasticity of material and design

(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 Ear,
Nose and Throat Devises

510(k) Number K021479

(Optional Format 1-2-96)