K071150

DEC 12 2007

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 17, 2007

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

Proprietary	Trocar Ventilation Tube
Common	Ventilation, Tympanostomy or Myringotomy Tube
Classification	Tube, Tympanostomy
Product Code	77 ETD
Regulation #	CFR 874.3880

2.5 Reason for Submission:

Change in design and inclusion of sterile, single-use trocar point

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

Temporary implant for ventilation and drainage of middle ear.

2.7 Modification of Existing Device: [807.92 (a)(3)]

K 973226 **Models:** Tuebingen, Tympanic (1 or 2 eyes), Beveled, Minimal
Cleared 11/04/1997

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

The umbrella-type implant comes mounted on a tiny single-use trocar point. Its penetrating edge penetrates the tympanic membrane and simultaneously forms a passage to draw the ventilation tube into that passage at a controlled rate until the ventilation tube is implanted. The trocar is immediately withdrawn. The procedure requires the use of a specially designed trocar handle.

The tubes are available with or without retention wires.

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

1. Elimination of need for prior paracentesis. Simultaenous incision of tympanic membrane and implant insertion
2. Considerably shorter procedure
3. Secure placement due to precise cut
4. Reduced incrustation susceptibility due to clean and precise cut
5. Minimal trauma as considerably less invasive than traditional VT placement

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 7.0 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 ventilation tube is provided in gilded silver or pure titanium. Both materials have a long history of safe and effective use. The trocar point and handle are manufactured of stainless surgical steel. The trocar point projects just enough to penetrate the membrane and to create the opening for positioning the ventilation tube. The precise cut and secure placement of the implant should reduce the risk of premature extrusion or

dislocation. The umbrella design of the ventilation tube – comparable to many others on the market – introduces no new risks. 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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2.13 COMPARISON of DESIGN + SAFETY and EFFECTIVENESS

Device	Trocar Ventilation Tube	Tübingen, Tympanic w/1 or 2 Eyelets, Beveled
510(k)	Pending	K-973226
Catalog #	1015 074, 1015 075 1015 076, 1015 077 w/retention wire	**Tübingen** 1015 020 – 1015 033 **T/Eyelets** 1015 064 – 1015 065 **Beveled** 1015 051 – 1015 056
Intended Use	Drainage and ventilation of middle ear subsequent to acute otitis media	Identical
Design	Umbrella or conic end on bobbin base mounted on sterile, single-use trocar tip which is withdrawn after implant placement	Typical bobbin shape, with eyelets, beveled opening, and others
Accessories	**Trocar Handle** (reusable) Cat. # 8000 143	None
# of Sizes	1	**Tübingen** 2 **T/Eyelets** 1 each **Beveled** 3
Diameters	**ID: 1.25 mm** **OD: 2.80 mm**	**Tübingen ID** 1.25/1.50 **OD** 2.55/2.80 **T/Eyelets ID** 1.50 **OD** 2.80/3.80/4.80 **Beveled ID** 0.75/1.25/1.50 **OD** 1.60/2.55/2.80
Implant Placement	Simultaneous Incision and Insertion	Insertion after prior paracentesis
Material	**Implant:** Titanium ASTM F67 & Gilded Silver **Trocar Tip & Handle:** 1.4305/AISI 303 Surg.Stainless Steel	**Implants** Gold-Platinum, Gilded Silver, Titanium
Single Use	**VT & Trocar Tip** Yes **Trocar Handle** Reusable	**Ventilation Tubes** Yes
Sterile	**VT & Trocar Tip** Yes **Trocar Handle** No	**Ventilation Tubes** Yes
Design Comparison	The tip extending into the tympanic cavity is conical; substantially equivalent bobbin base	Typical bobbin design, with eyelets, various openings
Safety & Effectiveness of Design Change [807.92 (b)(1)]	The simultaneous incision of the tympanic membrane/insertion of the tube significantly shortens the procedure while providing a controlled, precise cut for secure implant placement. This surgical technique should minimize patient trauma and reduce the risks of premature implant extrusion or dislocation. 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.**	

18/04/2007 12:10

Date 04/19/07

Signature

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Technical Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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DEC 1 2 2007

Heinz Kurz GmbH Medizintechnik
c/o Dagmar Maeser
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Amstel 320-1
Amsterdam, Netherlands D72144

Re: K071150
Trade/Device Name: Trocar Ventilation Tube
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy tube
Regulatory Class: Class II
Product Code: ETD
Dated: April 19, 2007
Received: April 25, 2007

Dear Ms. Maeser:

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.

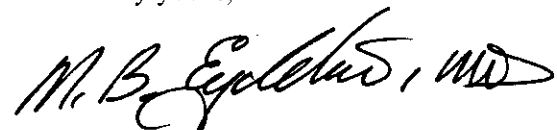
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K071150

Indications for Use

510(k) Number (if known):

Device Name: **Trocar Ventilation Tube**

Indications for Use: Temporary implant for ventilation or drainage of the middle ear.

Special Feature: Design eliminates need for prior paracentesis: Simultaneous incision and implant placement.

4/23/2007 5:17 PM

Prescription Use ___/___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen A Baker

ign-Off)
Ophthalmic Ear,
nroat Devises

Number K071150