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

K973226

NOV - 4 1997

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6. 510(k) SUMMARY

As required by Section 807.92(c)

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

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(2) **Identification of Devices** [807.92(a)(2)]

Trade Names	a.	Tübingen Ventilation Tube
	b.	Tympanic Ventilation Tube
	c.	DIABOLO Tympanic Ventilation Tubes
	d.	MINIMAL Typanic Ventilation Tube (Benz)
Common Name	Tympanostomy Tube; Ventilation Tube	
Classification Name	Tube, Tympanostomy	
Product Code	77 ETD	
Class	II	
Regulatory Number	874.3880	
Classification Panel	ENT Branch (HFZ-470)	

(3) **Identification of Predicate Devices** [807.92(a)(3)]

The KURZ ventilation tubes are substantially equivalent to a wide variety of ventilation tube designs produced by XOMED and XOMED-TREACE, Jacksonville, FL, USA and by Smith & Nephew Richards, Bartlett, TN, USA. In terms of indication, the short-term MINIMAL Ventilation Tube (Benz) is substantially equivalent to the Hubbard Airplane and the Tiny Tytan Vent Tubes, manufactured by Xomed-Treace.

These devices have been found substantially equivalent through the 510(k) premarket notification process.

510(k) Summary (Cont'd)

(4) Description of Devices [807.92(a)(4)]

a. Tübingen — Typical bobbin-shaped design made of gold-platinum, gold-plated silver, and titanium; with or without a wire for secure placement and removal. Internal diameter of Size 2 is min. 0.2 mm wider than that of most predicate devices (SE: Reuter Bobbin, Collar Button).

b. **Tympanic Ventilation Tube**

- **1 Eye** — Bobbin shape with unilateral eye extension of inner flange; made of gold-platinum alloy (SE: Spoon Bobbin, Shah Type Tube)
- **2 Eyes** — Bobbin shape with bi-lateral eye extensions of inner flange; made of gold-platinum alloy (SE: Most T-Tubes)

c. **DIABOLO Ventilation Tube**

External flange is cone-shaped to reduce the length of the internal hollow cylinder; made of gold-platinum alloy (SE: Beveled Bobbin; Shepard Grommets)

d. **MINIMAL Ventilation Tube (Benz)**

Narrow tube with sharpened end for insertion without prior paracentesis. Material: gold-plated stainless steel (1.4301).

The devices are implants for single patient use. They are sold in an indivi dual sterile package in a sealed carton.

(5) Intended Use of Devices [807.92(a)(5)]

KURZ precious metal tympanostomy tubes are intended to provide a means of aerating and draining the middle ear in patients with otitis media and to reduce the likelihood of recurrent postoperative middle ear infections for the duration in which the tube remains in situ.

The MINIMAL Ventilation Tube (Benz) has been designed for

1. temporary ventilation of the middle ear in secretory otitis media in adult patients for whom paracentesis alone is not sufficient, yet retention time of conventional ventilation tubes would be too long.
2. It can also effectively be applied in cases of narrow meatus, atrophic drum and post-tympanoplasty tube dysfunctions. Due to its tiny size (dia. 0.6 mm), insertion after tympanoplasty considerably reduces risk of permanent tympanum perforation.

Following surface anaesthesia, the tube is pushed through the tympanic membrane with alligator forceps without prior paracentesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 1997

Dagmar S. Maser
Business Support International
Heinz Kurz GmbH Medisintechnik
Amstel 320-1
1017 AP Amsterdam
The Netherlands

Re: K973226
Tympanostomy Tubes; Tüububgen Ventilation Tubes (Standard) Tympanic Ventilation Tube (with one eye); Tympanic Ventilation Tube (with 2 eyes); DIABLO Ventilation Tube and MINIMAL Ventilation Tube (Benz)
Dated: July 20, 1997
Received: August 27, 1997
Regulatory class: II
21 CFR 874.3880/Procode: 77 ETD

Dear Mr. Maser:

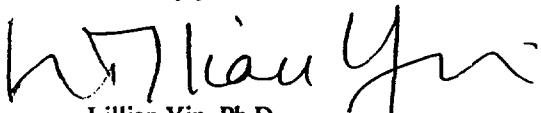
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K973226

Device Names Tübingen, Tympanic (1 or 2 eyes), DIABOLO Ventilation Tubes

INDICATIONS FOR USE:

Tympanic tubes are inserted into the eardrum (myringotomy) for drainage and temporary ventilation of the middle ear subsequent to acute otitis media.

Tympanic tubes with one or two eyes are designed to increase the retention time in the eardrum.

The substantially shortened passage of the DIABOLO reduces the length of the internal hollow cylinder and the smooth surface of the gold seems to diminish the risk of luminal occlusion.

Placement:

The tubes are placed in the tympanic membrane to provide the means for drainage of any fluid buildup in the middle ear while creating an avenue for the passage of air to equalize pressure on either side of the drum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David W. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973226

Prescription Use ✓ OR Over-The-Counter Use _____
(Per CFR 801 109)

(Optional Formal 1-2-96)

510(k) Number 973226 (10/06/97)

Device Names MINIMAL Tympanic Ventilation Tube (Benz)

INDICATIONS FOR USE:

1. Temporary ventilation of the middle ear in serous otitis media in adult patients.

2. In cases of narrow meatus, atrophic drum or post tympanoplasty tube dysfunction. Due to its tiny size (Diameter 0.6 mm), insertion after tympanoplasty considerably reduces the risk of permanent perforation of the tympanum.

This tympanic ventilation tube, constructed of gold-plated stainless steel (1.4301), has been designed for temporary ventilation in special cases in which paracentesis alone is not sufficient, yet retention time of conventional tubes would be too long. The tube features a sharpened end that can be pushed through the tympanic membrane with alligator forceps without prior paracentesis.

If the effusion is somewhat thicker than expected, an additional small paracentesis beside the tube is recommended, via which the mucous tympanum can easily be aspirated due to the pressure balance which is achieved through the ventilation tube.

Should secretion encrustation occur, the MINIMAL Ventilation Tube can be replaced without the need for surface anaesthesia and without pain to the patient as it has no internal flange but is kept in position through tissue tension.

Placement:

Following surface anaesthesia, the tube is pushed through the tympanic membrane with alligator forceps without prior paracentesis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973226

Prescription Use ✓ OR Over-The-Counter Use _____
(Per CFR 801 109)