K972585

6. 510(k) SUMMARY

AUG - 4 1997

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

As required by Section 807.92(c)

Heinz Kurz GmbH
Medizintechnik

Hausanschrift:
Tübinger Straße 3
D-72144 Dußlingen

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

Dagmar S. Mäser
Business Support International
Amstel 320-I
Amsterdam, 1017AP
The Netherlands

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

Trade Name	Aerial Prosthesis
Common Name	Total Ossicular Replacement Prosthesis (TORP)
Classification Name	Middle-Ear, Replacement, Ossicular Prosthesis, Total
Product Code	77 ETA
Class	II
Regulatory Number	874.3495

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

The KURZ Aerial total ossicular implants are substantially equivalent to total ossicular devices of Smith & Nephew Richards and Xomed (with Ionos). These devices have been found substantially equivalent through the 510(k) premarket notification process.

(4) **Description of Device** [807.92(a)(4)]

a. **Gold** **Standard** The implant consists of a golden wire rectangle with a structured outer surface and a stem which is available in various lengths. It ends in a 'bell' with two slits.

Dresden The implant consists of an extremely thin mesh plate made of gold and a thin shaft, which is available in different lengths. It has a split piston at the end.

b. **Titanium** **Düsseldorf** The implant consists of a titanium mesh plate that is textured on the surface that makes contact with the tympanum and a shaft that is available in various lengths.

Tübingen The prosthesis consists of a titanium mesh plate that is connected eccentrically with a shaft available in various lengths. A hollow piston, open at the bottom, the inside of which is also textured, is located at the end of the shaft.

510(k) Summary (Cont'd)

The device is a single patient use only implant. It comes in an individual sterile package in a sealed carton.

(5) Intended Use of Device [807.92(a)(5)]
The KURZ Aerial implants are intended for the elective reconstruction of the ossicular chain to facilitate conduction of sound energy from the ear drum to the inner ear. The prosthesis is implanted into the middle ear during a tympanoplasty procedure and is retained in the middle ear by the design configuration of the device and the favorable bio-compatible characteristics of gold and titanium.

The device can be used on adults and children.

(6) Technological Characteristics [807.92(a)(6)]
The implants can be bent and easily shaped to the individual conditions in the middle ear, yet hold their shape after placement.

(7) Information Bearing on the Safety and Effectiveness
The KURZ Aerial total ossicular replacements have the same intended use as predicate devices. There are no additional characteristics known that should adversely affect the safety and effectiveness of these implants.

Signature _____ Date July 7, 1997
Dagmar S. Mäser

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 1997

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

Re: K972585
Heinz Kurz GmbH Medizintechnik
Dated: July 7, 1997
Received: July 10, 1997
Regulatory class: II
21 CFR 874.3495/Procode: 77 ETA

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 _____

Device Name **Aerial Prosthesis**

INDICATIONS FOR USE:

Ossicle replacement in case of interrupted sound conducting chain and intact, mobile stapes footplate.

The Aerial Total Prosthesis is intended for bridging a complete auditory ossicle defect.

The prosthesis is placed on the basis of the stapedis and the defect is bridged as far as the ear drum or up to the manubrium mallei.

(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 K978585

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

KRZ-USE.IND

(Optional Formal 1-2-96)