K99 3583

NOV 10 1999

stryker LEIBINGER

4100 East Milham Avenue
Kalamazoo, MI 49001
Phone (616) 323-7700
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510(k) Summary

Device Name:

Trade Name:	Zürich Titanium Ossicular Replacement System
Common Names:	Total ossicular replacement prosthesis Partial ossicular replacement prosthesis
Classification Names:	Total ossicular replacement prosthesis: 21 CFR 874.3495, Class II Partial ossicular replacement prosthesis: 21 CFR 874. 3450, Class II

Device Sponsor:

Manufacturer:	Stryker Corporation Stryker Leibinger GmbH and Co. KG Boetzinger Straβe 41 D-79111 Freiburg Germany Registration No.: 8010177
Distributor:	Stryker Corporation Stryker Leibinger 4100 E. Milham Avenue Kalamazoo, MI 49001 Registration No.: 1811755

Regulatory Class: Class II

Date Prepared: October 21, 1999

Summary of Safety and Effectiveness:

The Zürich Titanium Ossicular Replacement System is intended to be used for ossicle replacement to restore middle ear function when the sound transmission chain is broken. The various prosthetic models are implanted for partial or complete reconstruction to replace missing, malformed, or immobile ossicles or in secondary procedures after tumor or trauma operations.

The system consists of various implants, instrumentation, and storage containers.

The substantial equivlance of this device is based on the equivalence in intended use, materials, design, and operational principles to the currently marketed predicate devices such as the Micromedics S&T Total Ossicular Replacement Prosthesis and the Tubingen Titanium Prosthesis (TTP) Vario (Heinz Kurz GmbH Medizintechnik).

By: Nicole Petty

Nicole Petty
Regulatory Affairs Analyst

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Ms. Nicole Petty
Stryker Corporation
Regulatory Affairs Analyst
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K993583
Device: Zurich Titanium Ossicular Replacement System, Titan Stapes Prosthesis, Titan Incus Prosthesis, Titan TORP, and Titan Neomalleus Prosthesis
Dated: October 21, 1999
Received: October 22, 1999
Classification Regulation: 77 ETA , 21 CFR 874.3495
77 ETB , 21 CFR 874.3450
Regulatory Class: II

Dear Ms. Petty:

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 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,

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

Enclosure

510(k) Number: K993583

Device Name: Zürich Titanium Ossicular Replacement System

Indications For Use: The Leibinger titanium ossicular chain reconstruction prostheses and accessories are used for ossicle replacement to restore middle ear function when the sound transmission chain is broken. The various prosthetic models are implanted for partial or complete reconstruction, to replace missing or malformed ossicles or in secondary procedures after tumor or trauma operations.

Titanium ossicular chain reconstruction prostheses are available for the following indications:

- Chronic otitis media
- Immobility of the stapes (otosclerosis in particular)
- Injury of the ossicle (trauma)
- Abnormal and defective formation of the middle ear
- Secondary procedure to improve hearing
- Revision operation on a malpositioned prosthesis

Product Designation	Product Intended Use
Stapes prosthesis	Flat band and piston prosthesis for attachment to the malleus or incus, inserted through the footplate of the stapes.
Total prosthesis (TORP)	Plate prosthesis with shaft and shoe as ossicle replacement between the tympanic membrane and the footplate of the stapes.
Neomalleus total prosthesis	Malleus prosthesis as ossicle replacement in combination with stapes prosthesis. —
Incus prosthesis	Incus replacement to connect malleus and head of stapes.
Partial prosthesis (PORP)	Malleus and incus replacement to connect tympanic membrane and head of stapes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/9/99

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K993583

(Optional Format 3-10-98)

Prescription device ✓