Karl Storz
Endoscopy-America, Inc.

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K043375

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

Contact: Yvonne Fernandez
Sr. Regulatory Affairs Associate

Device Identification:

Common Name: Total ossicular replacement prostheses
Partial ossicular replacement prostheses

Trade Name: FISCH Titanium Middle Ear Prostheses

- *FISCH Titanium Total Prosthesis*
- *FISCH Titanium Stapes Piston (7.0 mm, 8.5 mm, 10.0 mm)*
- *FISCH Titanium Incus Prosthesis (3.0 mm, 4.0 mm, 5.0 mm)*
- *FISCH Titanium Neomalleus Prosthesis*

Indication: The FISCH Titanium Middle Ear Prostheses are intended 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.

Device Description: The FISCH Titanium Middle Ear Prostheses are made of anodized titanium, which is commonly used in medical devices for a wide range of application and has a long history of biocompatibility for human use.

Substantial Equivalence: The FISCH Titanium Middle Ear Prostheses are substantially equivalent to the predicate devices since the basic features and intended use are similar. The minor difference between the FISCH Titanium Middle Ear Prostheses and the predicate devices raise no new issues of safety and effectiveness, as these minor differences have no effect on the performance, function or intended use of the device. See Tables 1-4 for a detailed comparison.

TABLE 1: Stryker/Leibinger FISCH Titanium Stapes Prosthesis Comparison to Karl Storz FISCH Titanium Stapes Prosthesis

DEVICE	STRYKER/ LEIBINGER - FISCH TITANIUM STAPES PISTON (K993583)			KARL STORZ - FISCH TITANIUM STAPES PISTON		
1. INTENDED USE	Flat band and piston prosthesis for attachment to the malleus or incus, inserted through the footplate of the stapes.			Same		
2. DIMENSIONS BY MODEL #	13-18040	13-18042	13-18044	227510	227511	227512
Overall Length	7.00 mm	8.5 mm	10.00 mm	7.00 mm	8.5 mm	10.00 mm
Piston Diameter	0.4 mm	0.4 mm	0.4 mm	0.4 mm	0.4 mm	0.4 mm
3. MATERIAL	Titanium			Same		
4. SINGLE USE	Yes			Same		
5. STERILE	Yes			Same		
6. DESIGN COMPARISON	One-piece design, flat loop to enable a stable connection with the incus or malleus.			Same		

TABLE 2: Stryker/Leibinger FISCH Titanium Incus Prosthesis Comparison to Karl Storz FISCH Titanium Incus Prosthesis

DEVICE	STRYKER/ LEIBINGER - FISCH TITANIUM INCUS PROSTHESIS (K993583)			KARL STORZ - FISCH TITANIUM INCUS PROSTHESIS		
1. INTENDED USE	Incus replacement to connect malleus and head of stapes.			Same		
2. DIMENSIONS BY MODEL #	13-18030	13-18031	13-18032	227515	227516	227517
Length	3.00 mm	4.0 mm	5.0 mm	3.00 mm	4.0 mm	5.0 mm
OD	2.0 mm	2.0 mm	2.0 mm	2.0 mm	2.0 mm	2.0 mm
OD - Tapered End	1.3 mm	1.3 mm	1.3 mm	1.3 mm	1.3 mm	1.3 mm
3. MATERIAL	Titanium			Anodized Titanium		
4. SINGLE USE	Yes			Same		
5. STERILE	Yes			Same		
6. DESIGN COMPARISON	Design allows intraoperative shaping; 4 holes to pick up and manipulate			Same		

TABLE 3: Stryker/Leibinger FISCH Titanium Neomalleus Prosthesis Comparison to Karl Storz FISCH Titanium Neomalleus Prosthesis

DEVICE	STRYKER/LEIBINGER - FISCH TITANIUM NEOMALLEUS PROSTHESIS (K993583)	KARL STORZ- FISCH TITANIUM NEOMALLEUS PROSTHESIS
1. INTENDED USE	Malleus replacement in combination with the stapes prosthesis.	Same
2. DIMENSIONS BY MODEL #	13-18020	227522
Length	5.0 mm	5.0 mm
OD - Grooved End	1.1 mm	1.1 mm
OD - Smooth End	0.5 mm	0.5 mm
3. MATERIAL	Titanium	Anodized Titanium
4. SINGLE USE	Yes	Same
5. STERILE	Yes	Same
6. DESIGN COMPARISON	Smooth end for insertion with the traga perichondrium; grooves for attachment to stapes piston	Same

TABLE 4: Stryker/Leibinger FISCH Titanium Total Prosthesis Comparison to Karl Storz FISCH Titanium Total Prosthesis

DEVICE	STRYKER/LEIBINGER - FISCH TITANIUM TOTAL PROSTHESIS (K993583)	KARL STORZ- FISCH TITANIUM TOTAL PROSTHESIS
1. INTENDED USE	Plate prosthesis with shaft and shoe as replacement between the tympanic membrane and the footplate of the stapes.	Same
2. DIMENSIONS BY MODEL #	13-18090	227520
Length	10.0 mm	Same
Shaft Diameter	0.6 mm	Same
Head Plate Diameter	5 mm	Same
3. MATERIAL	Titanium	Anodized Titanium
4. SINGLE USE	Yes	Same
5. STERILE	Yes	Same
6. DESIGN COMPARISON	Direct connection between tympanic membrane and footplate; may be trimmed to size; spike on foot for stable attachment	Same

Signed: _____

Yvonne Fernandez / Sr. Regulatory Affairs Associate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2005

Karl Storz Endoscopy- America, Inc.
c/o Ms. Yvonne Fernandez
Sr. Regulatory Affairs Associate
600 Corporate Pointe, 5th Floor
Culver City, CA 902307

Re: K043375
Trade/Device Name: FISCH Titanium Middle Ear Prostheses
Regulation Number: 21 CFR 874.3495; 874.3450
Regulation Name: Total ossicular replacement prostheses; Partial ossicular replacement prostheses
Regulatory Class: Class II
Product Code: ETA; ETB
Dated: December 7, 2004
Received: December 8, 2004

Dear Ms. Fernandez:

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 Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K043375

Indications for Use

510(k) Number (if known): Not yet assigned

Device Name: FISCH Titanium Middle Ear Prostheses

Indications for Use: The FISCH Titanium Middle Ear Prostheses are intended 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K043375