K991324

MAY 18 1999

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

510(K) – 77 KHJ

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2. 510(k) SUMMARY
of Safety and Effectiveness
+
SE Comparison Table

Heinz Kurz GmbH Medizintechnik
As required by Section 807.92

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 16, 1999

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

Proprietary	Titanium Vocal Fold Medializing Implant (TVFMI)
Common	Vocal Cord Medialization Implant
Classification	Polymer, ENT Synthetic – Polyamide (Mesh or Foil Material)

2.5 Reason for Submission: [807.81(2)]

New Device

2.6 Predicate Devices [807.92(a)(3)]

2.6.1	**Manufacturer**	**Boston Medical Products, Inc. K 972317**
	Proprietary Name	Montgomery Thyroplasty Implant System
	Catalog #'s	MTF– 06 to MTF– 10 (female) MTM -08 to MTM- 12 (male)
2.6.2	**Manufacturer**	**Smith & Nephew Enterprises K 974311**
	Proprietary Name	VoCoM (Vocal Cord Medialization) Implant
	Catalog #'s	14-3000 to 14-3008

2.7 Device Description: [807.92(a)(4)]

The KURZ TVFMI is made of medical grade, smoothly finished titanium.

The preformed titanium sheet implant can be adjusted intra-operatively to exactly fit the anatomic conditions and size of the patient. The angular shape, the bent flanges and the fastening with monofilament non-absorbable sutures prevent implant dislocation with great certainty.

The device comes in two (2) sizes - one each for mostly female and male patients.

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

Like the SE devices, the KURZ TVFMI is intended for use in medialization thyroplasty in patients with unilateral vocal fold paralysis and incomplete glottis closure during phonation and/or swallowing.

2.9 Difference of Technological Characteristics when Compared to SE Devices [807.92 (a)(6)]

The KURZ TVFMI material is titanium while SE devices are made of silicone [Boston Medical] and dense hydroxylapatite [S&N]. Like the SE devices, the TVFMI is preformed.

The simple design corresponds to the anatomic location. Fastening with monofilament non-absorbable sutures prevents dislocation.

The titanium can easily be adjusted in length and shape to the individual patient; therefore, only one size each for (mostly) male and female patients is required leading to a standardization of the procedure and considerably reduced inventory and health care costs. By comparison, the Montgomery Thyroplasty Implant comes in ten (10) sizes (5 each for female and male patients) and VoCoM in five (5).

2.10 Discussion of Safety and Effectiveness [807.92(b)]

Clinical results[1] to date have shown that the KURZ TVFMI compares favorably with SE devices regarding safety and effectiveness and exhibits the following additional features:

2.10.1 Minimal Implant Adjustments During Operation

Due to its balance of elasticity and rigidity, the titanium sheet is easily bent (to create the exact tension required to securely hold the implant in the ventral section) and otherwise adjusted to meet the needs of the individual patient. These adjustments are permanently 'remembered'[2] by the titanium, i.e. they hold that shape after implantation.

2.10.2 Good Fixation

The design assures optimal fixation and stabilization, thus minimizing the danger of dislocation. Implant movement is further eliminated by fastening with monofilament nonabsorbable sutures.

Extrusion of the implant after removal of the cartilage is highly unlikely, if not impossible.

2.10.3 Simplified and Shortened Procedure

The TVFMI comes only in two sizes (male, female) that can easily be adjusted to meet individual patient requirement. As a result, the surgical procedure has been simplified and shortened, thus improving the results due to reduced intralaryngeal swelling and hematoma.

2.10.4 Biocompatibility

ASTM F67 medical grade titanium has a proven record of excellent biocompatibility.

2.10.5 MRI

Testing in a 0.5 Tesla nuclear magnetic resonance tomograph has revealed no implant movement and no adverse tissue effects attributable to MRI-generated heating. The image quality may be

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[1] Exhibit 2: *Titanium Vocal Fold Medializing Implant: Introducing a Novel Implant System for External Vocal Fold Medialization* by Gerhard Friedrich, MD; reprint from *ANNALS OF OTOLOGY, RHINOLOGY & LARYNGOLOGY*, Jan. 99, Vol. 108, No. 1

[2] The implant retains the new shape after exceeding the elastic yield point, i.e. the phase boundary between the elastic and plastic phase of titanium.

impeded or blurred in direct vicinity of the implant. To date, no report of adverse effects has come to the attention of the manufacturer.

2.10.6 Easy Handling

The implantation technique and handling are simple and time-saving, thus shortening the operation time and improving the results.

Due to the special design, the TVFMI is self-locking anteriorly because of its U-shape. The cartilage window is cut approx. 2 mm smaller than the implant length so that the TVFMI has to be inserted under slight tension. It expands in the endolarynx, snaps into place and automatically stabilizes its position.

2.10.7 Voice Parameters

At least equal, if not better improvement of all voice parameters can be achieved when compared to SE devices (s. Exh. 2, p. 80 re voice function tests and p. 81 for overview table of pre/postoperative glottal gap + voice dysfunction index).

2.11 Industry Standards: [807.92 (d)]

KURZ certifies compliance with required ISO/EN/ASTM/AAMI/ANSI and other device-related standards that apply to the manufacture, packaging, labeling, sterilization, and reprocessing (of custom instruments) of subject devices including the validation of these processes.

2.12 Information Bearing on the Safety and Effectiveness:

[807.92 (b)(3)]

The KURZ TVFMI implant has the same intended use as the predicate devices. The different material (titanium) and other design do not adversely affect the safety and effectiveness of these implants, but rather enhance biocompatibility, implant stability, and voice results achieved.

The results of design validation and clinical testing raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1999

Ms. Dagmar S. Maeser
Business Support Intl.
Amstel 320-I
1017 AP Amsterdam
The Netherlands

Re: K991324
Trade Name: Titanium Vocal Fold Medializing Implant (TVFMI)
Regulatory Class: II
Product Code: 77 KHJ
Dated: April 16, 1999
Received: April 19, 1999

Dear Ms. Maeser:

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 K991324

Device Name Titanium Vocal Fold Medializing Implant (TVFMI)

Classification Polymer, ENT Synthetic –Polyamide (Mesh or Foil Material)

Product Code 77 KHJ **Class II** **21 CFR 874.3620**

INDICATIONS FOR USE

Incomplete glottis closure during phonation and/or swallowing, especially unilateral vocal cord paralysis.

The TVFMI and custom accessories are exclusively intended for use by qualified medical personnel trained in laryngosurgical techniques.

(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 Ophthalmic Devices
510(k) Number K991324

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

(Optional Format 1-2-96)