

510K(k) SUMMARY

SUBMITTER: Specialities Remeex International, s.l.
C/Tren De Baix,
55 Gaixos Terrassa
Barcelona, Spain 08223

DATE PREPARED: October 12th 2006

DEC 19 2006

DEVICE NAME: NEEDLELESS SLING

CLASSIFICATION NAMES: Mesh, Surgical, Polymeric

PREDICATE DEVICES:

1. GYNECARE TENSION FREE VAGINAL TAPE SYSTEM
2. GYNECARE TVT SECUR SYSTEM

Device Description:

The NEEDLELESS SLING is included in the sling techniques for the treatment of female stress urinary incontinence. This device is a vaginal sling that permits for the regulation of continence in the female incontinent patient. This system uses a mesh sling, placed under the urethra, that can be regulated during the intervention and just after it to achieve continence. The sling is passed through the endopelvic fascia, creating a fibrosis that supports the mid urethra as a limitation to its descending and thus providing continence.

Predicate Devices:

There has been a device previously cleared by the FDA in the following 510(K) Notifications indicated as a pubourethral sling for the treatment of female stress urinary incontinence:

Device	510(k) Document Number	Date Cleared	Indications
Gynecare Tension-Free Vaginal Tape System	K012628	10/26/2001	Female Urinary Incontinence
Gynecare TVT Secur System	K052401	11/28/2005	Female Urinary Incontinence

Technologically, both the proposed and predicate devices are the same (i.e. both are meshes that provide pubourethral support) and are indicated for the treatment of female urinary incontinence. Any differences between the two devices do not raise new questions of safety and effectiveness.

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Intended Use:

NEEDLELESS SLING Indications:

The NEEDLELESS SLING is indicated for the treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency

Technological Characteristics:

Technologically, both the new device and the predicate device are the same (i.e. both are meshes that provide pubourethral support). The form, fit, function and method of operation are similar. Any differences between the two devices do not raise new questions of safety and effectiveness

Performance Data:

Results of verification testing indicates that the product meets the established performance requirements

Conclusions:

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the proposed device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Specialities Remeex International S.L.
% Mr. Jeffrey R. Shideman
President
International Medical Products Corporation
7307 Gloucester Drive
EDINA MN 55435

SEP 28 2012

Re: K063136
Trade/Device Name: NEEDLESS SLING
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: October 12, 2006
Received: November 7, 2006

Dear Mr. Shideman:

This letter corrects our substantially equivalent letter of December 19, 2006.

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 (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 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.

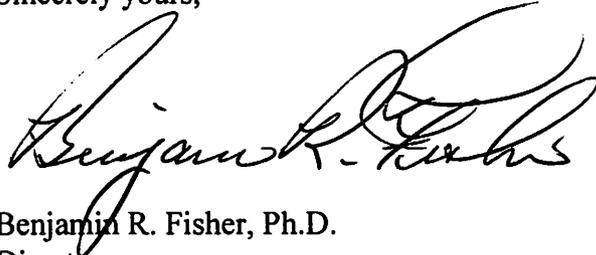
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with the first name being the most prominent.

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063136

Device Name: NEEDLELESS SLING

Indications for Use:

The NEEDLELESS SLING is indicated for the treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency

Prescription Use (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)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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CONFIDENTIAL

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