OCT 17 2005

K052175

Section 8: 510(k) Summary

Date Prepared	August 9, 2005
New Device Name	I-STOP™ Mid-Urethral Sling
Predicate Device	Tension Free Vaginal Tape (TVT) System; Ethicon, Inc. (K974098)
Contact	Uroplasty, Inc. 2718 Summer Street NE Minneapolis, MN 55413-2820 Telephone: (612) 378-1180, Facsimile: (612) 378-2027 info.usa@uroplasty.com

Intended Use

The I-STOP Mid-Urethral Sling is intended for the treatment of female stress urinary incontinence (SUI) due to urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Device Description

The I-STOP Device is comprised of a non-resorbable polypropylene material woven into a mesh with each end attached to a polyethylene clip, two technique-dependant stainless steel implantation needles and two polycarbonate needle handles. The device is EtO sterilized and intended for single-use only.

Indications Statement

The I-STOP Mid-Urethral Sling is intended for the treatment of female stress urinary incontinence due to urethral hypermobility and/or intrinsic sphincter deficiency. Four different I-STOP models allow for implantation of the I-STOP mesh via retropubic (transvaginal or suprapubic) or transobturator (outside-in or inside-out) approaches.

Technological Characteristics

The new and predicate devices are technologically the same; they are polypropylene meshes implanted with stainless steel needles to provide urethral support for females patients with SUI. The devices have similar implantation, sterilization, and storage requirements. In the few instances where the devices differ, no additional concerns about safety or effectiveness are raised.

Performance

Clinical experience with the I-STOP device has demonstrated that it successfully and safely functions as intended. Additional biocompatibility testing supports the safety profile of the I-STOP Sling.

Conclusion

The I-STOP Mid-Urethral Sling is substantially equivalent to the predicate device, the Tension Free Vaginal Tape (TVT) from Ethicon, Inc. (K974098).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Mr. Michael Morrell, RAC
Director of Regulatory Affairs
Uroplasty, Inc.
2718 Summer Street NE
Minneapolis, Minnesota 55413-2820

Re: K052175
Trade/Device Name: I-STOP™ Mid-Urethral Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 9, 2005
Received: August 11, 2005

Dear Mr. Morrell:

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 (240) 276-0115. 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,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION [510(k)] SUBMISSION
I-STOP™ MID-URETHRAL SLING

Indication for Use Statement

510(k) Number: K052175

New Device Name: I-STOP™ Mid-Urethral Sling

Indication for Use: The I-STOP Mid-Urethral Sling is intended for the treatment of female stress urinary incontinence (SUI) due to urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

(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 General, Restorative, and Neurological Devices

510(k) Number K052175