

K974098

JAN 28 1998

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

New Device

Name: Tension Free Vaginal Tape (TVT) System

Predicate Device

Name: ProteGen Sling Collagen Impregnated Material

510(K) SUMMARY

Device Description

The Tension Free Vaginal Tape (TVT) System is comprised of three components; the device (TVT device) and its accessories (TVT Introducer and TVT Rigid Catheter Guide). Each is available separately for use at the surgical site. The TVT device is composed of PROLENE polypropylene mesh (tape). The mesh is covered with a polyethylene sheath with a slit in the middle. Both the mesh and sheath are attached to two (2) stainless steel needles. The TVT Introducer (accessory) is made of stainless steel. It is composed of three (3) parts; handle, threaded shaft and rubber O-ring. The introducer functions to facilitate passage of the TVT device from the vagina to the abdominal skin. The TVT Rigid Catheter Guide is made of stainless steel and used to add rigidity to the Foley Catheter during the surgical procedure.

Intended Use

The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

**Indications
Statement**

The TVT device is a sterile, single-use device intended to be used as a pubourethral sling indicated for treatment of stress urinary incontinence, for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT Introducer and Rigid Catheter Guide accessories are intended to facilitate placement of the TVT device. The accessories, available separately, are provided non-sterile and are reusable.

**Technological
Characteristics**

Technologically both the new device and predicate device are the same (i.e. both are meshes that provide pubourethral support). Additionally, both devices utilize accessories for use in the surgical procedure. Any differences between the two devices do not raise new questions of safety and effectiveness.

Performance Data

Results of clinical evaluations were used to show that the TVT System functioned as clinically intended. Sufficient data has been gathered from clinical testing to assess that the TVT System performs as clinically intended.

Conclusions

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

Contact

Gregory R. Jones
Director
Regulatory Affairs
ETHICON, Inc.
Rt. #22 West
Somerville, NJ 08876-0151

Date

October 28, 1997 .



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

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Inc.
P.O. Box 151
SOMERVILLE NJ 08876

SEP 28 2012

Re: K974098
Trade/Device Name: Tension Free Vaginal Tape (TVT) System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: October 29, 1997
Received: October 30, 1997

Dear Mr. Jones:

This letter corrects our substantially equivalent letter of January 28, 1998.

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.

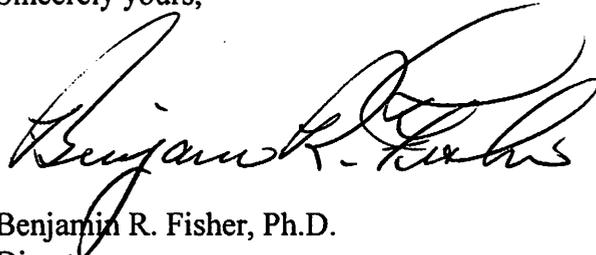
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: Tension Free Vaginal Tape (TVT) System

Indications for Use: The TVT device is a sterile, single-use device intended to be used as a pubourethral sling indicated for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT Introducer and Rigid Catheter Guide accessories are intended to facilitate placement of the TVT device. The accessories, available separately, are provided non-sterile and are reusable.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

[Signature] (Optional Format 1-2-9G)
(Division 5, 201 Off)
Federal Register Re services
510(k) number K974020

Tension Free Vaginal Tape (TVT) System
ETHICON, Inc.