June 28, 2018

Ethicon, Inc
Julie Tom Wing
Senior Regulatory Affairs Program Lead
P.O. Box 151, Route 22 West
Somerville, New Jersey 08876

Re: K173162
Trade/Device Name: GYNECARE TVT™ Abdominal Guides and Couplers, GYNECARE TVT™ Reusable Introducer, GYNECARE TVT™ Reusable Rigid Catheter Guide
Regulation Number: 21 CFR 21 CFR 884.4910
Regulation Name: Specialized surgical instrumentation for use with urogynecologic surgical mesh
Regulatory Class: Class II
Product Code: PWJ
Dated: May 24, 2018
Received: May 29, 2018

Dear Julie Tom Wing:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173162

Device Name
GYNECARE TVT™ Abdominal Guides and Couplers, GYNECARE TVT™ Reusable Introducer, GYNECARE TVT™ Reusable Rigid Catheter Guide

Indications for Use *(Describe)*

The GYNECARE TVT™ Abdominal Guides and Couplers are single use devices used to facilitate placement of the GYNECARE TVT™ device when placed in a top-down retropubic fashion (also known as an abdominal approach).

The GYNECARE TVT™ Reusable Introducer is a reusable device intended to aid in the placement of the GYNECARE TVT™ device retropubically.

The GYNECARE TVT™ Reusable Rigid Catheter Guide is a reusable device intended to facilitate the identification of the urethra and bladder neck during the placement of the GYNECARE TVT™ device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ETHICON
a Johnson & Johnson company

510(k) Summary – K173162

Submitter:	Ethicon Women's Health and Urology A Division of Ethicon, Inc. a Johnson & Johnson company P.O. Box 151 Route 22 West Somerville, NJ 08876-0151
Contact Person:	Julie Tom Wing, M.S. Senior Regulatory Affairs Program Lead Ph: (908) 218-5648 Fax: (908) 218-2595 Email: jtomwing@its.jnj.com
Date Prepared:	June 27, 2018
Device Trade Name:	GYNECARE TVT™ Abdominal Guides and Couplers GYNECARE TVT™ Reusable Introducer GYNECARE TVT™ Reusable Rigid Catheter Guide
Common Name:	Specialized urogynecologic surgical mesh instrumentation
Regulation Name:	Specialized surgical instrumentation for use with urogynecologic surgical mesh
Regulation Number:	21 CFR 884.4910

Regulatory Class: II

Product Code: PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

Predicate Device:

GYNECARE TVT™, Ethicon Women's Health and Urology, 510(k) K012628.

The predicate device has not been subject to a design related recall.

Device Description

The subject devices included the following components:

GYNECARE TVT™ Reusable Introducer

GYNECARE TVT™ Reusable Rigid Catheter Guide

GYNECARE TVT™ Abdominal Guides and Couplers

The subject devices are intended to be used with the GYNECARE TVT™ sling intended to treat stress urinary incontinence.

GYNECARE TVT™ Reusable Introducer

The GYNECARE TVT Introducer is provided non-sterile and is reusable. The Introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The Introducer is intended to facilitate the passage of the GYNECARE TVT Device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

GYNECARE TVT™ Reusable Rigid Catheter Guide

The GYNECARE TVT Rigid Catheter Guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

GYNECARE TVT™ Abdominal Guide

The GYNECARE TVT abdominal guide is a sterile disposable instrument intended to facilitate passage of the GYNECARE TVT device. Two abdominal guides are included in each kit with the GYNECARE TVT couplers.

GYNECARE TVT™ Coupler

The GYNECARE TVT coupler is a sterile disposable polypropylene connector used to connect the GYNECARE TVT abdominal guide to the GYNECARE TVT needle. Two couplers are included in each kit with abdominal guides.

Indications for Use

The GYNECARE TVT™ Abdominal Guides and Couplers are single use devices used to facilitate placement of the GYNECARE TVT™ device when placed in a top-down retropubic fashion (also known as an abdominal approach).

The GYNECARE TVT™ Reusable Introducer is a reusable device intended to aid in the placement of the GYNECARE TVT™ device retropubically.

The GYNECARE TVT™ Reusable Rigid Catheter Guide is a reusable device intended to facilitate the identification of the urethra and bladder neck during the placement of the GYNECARE TVT™ device.

Summary of Substantial Equivalence Comparison

The following table compares the subject and predicate device.

Device & Predicate Device(s):	K173162	K012628
Indications for Use Statement	The GYNECARE TVT Reusable Introducer is a reusable device intended to aid in the placement of the GYNECARE TVT Device, retropubically. The GYNECARE TVT Reusable Rigid Catheter Guide is a reusable device intended to facilitate the identification of the urethra and bladder neck during the placement of the GYNECARE TVT Device. The GYNECARE TVT Abdominal Guides and Couplers are single use devices used to facilitate placement of the GYNECARE TVT Device when placed in a top-down retropubic fashion (also known as an abdominal approach).	The TVT device is 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, rigid catheter guide and TVT abdominal guides and couplers are accessories intended to facilitate placement of the TVT device.

Operating Principle	Aid in placement of surgical mesh	Treatment of women with stress urinary incontinence
Patient Contact Duration	< 24 hours (tissue/bone)	Permanent (tissue/bone)
Device Design	Instrumentation	Mesh
Device Materials	Stainless steel Polycarbonate Polypropylene	Woven polypropylene

The subject devices have different indications for use statements compared to the predicate device, as the predicate device is a surgical mesh system that is indicated to treat stress urinary incontinence. However, the intended use of the subject and predicate device is the same, because the subject devices are accessories to the predicate surgical mesh.

As described in the table above, the operating principle, patient contact, device design, and device materials are different between the subject and predicate devices. The predicate device is a surgical mesh, whereas the subject devices are used for the placement of surgical mesh. The differences between the subject and predicate device can raise different questions of safety and effectiveness, as we are comparing an accessory and parent device. However, the subject devices are accessories to the predicate devices. The differences in technological characteristics were evaluated through completion of special controls (performance testing, biocompatibility, shelf-life/reprocessing, labeling, and sterilization) published in the final order reclassifying urogynecologic surgical mesh instrumentation from class I to class II published on January 6, 2017.

Summary of Performance Testing

The following performance tests were completed on the subject devices:

- Sterilization validation
- Reprocessing validation
- Package integrity
- Dimensional and mechanical performance
- Biocompatibility
    - Cytotoxicity
    - Sensitization
    - Irritation
- Shelf life

The results of performance testing demonstrate the subject devices are sterile to an SAL for 10^{-6}, biocompatible, have sufficient mechanical performance for their intended use, have a validated shelf life, and that the GYNECARE TVT Introducer and

GYNECARE TVT Rigid Catheter Guide reusable devices can be adequately reprocessed.

Conclusion

The subject devices are substantially equivalent to the predicate device and meet the special controls outlined in 21 CFR 884.4910, specialized surgical instrumentation for use with urogynecologic surgical mesh.