August 10, 2018

Ethicon, Inc.
Debbie Fazen, Ph.D.
Senior RA Program Lead
Route 22 West
Somerville, NJ 08876

Re: K181151
Trade/Device Name: GYNECARE TVT ABBREVO™ and GYNECARE TVT™ Obturator Helical Passers and Atraumatic Winged Guide
Regulation Number: 21 CFR§ 884.4910
Regulation Name: Specialized Surgical Instrumentation for use with Urogynecologic Surgical Mesh
Regulatory Class: II
Product Code: PWJ
Dated: July 11, 2018
Received: July 12, 2018

Dear Debbie Fazen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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)*
K181151

Device Name
GYNECARE TVT ABBREVO™ and GYNECARE TVT™ Obturator Helical Passers and Atraumatic Winged Guide

Indications for Use *(Describe)*
The Gynecare TVT ABBREVO™ Helical Passers and Atraumatic Winged Guide are intended to aid in the placement of the GYNECARE TVT ABBREVO™ device.

The Gynecare TVT™ Obturator Helical Passers and Atraumatic Winged Guide are intended to aid in the placement of the GYNECARE TVT™ Obturator 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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:	Debbie Fazen Manager, Regulatory Affairs Ph: (908) 218-3196 Fax: (908) 218-2595 Email: Dfazen@its.jnj.com
Date Prepared:	August 9, 2018
Device Trade Names:	GYNECARE TVT ABBREVO™ and GYNECARE TVT™ Obturator Helical Passers and Atraumatic Winged Guide
Common Names:	Specialized urogynecological surgical mesh instrumentation
Regulatory Class:	II
Regulation Number:	21 CFR 884.4910 – Specialized surgical instrumentation for use with urogynecologic surgical mesh
Product Code:	PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

Predicate Devices:

Device	Company	Product Code	510(k) Number
GYNECARE TVT ABBREVO™ Continence System (Helical Passers and Winged Guide)	Ethicon, Inc.	OTN	K100936
GYNECARE TVT Obturator Continence System (Helical Passers and Winged Guide)	Ethicon, Inc.	OTN	K033568

The predicate devices have not been subject to a design related recall.

Device Description

The GYNECARE TVT ABBREVO™ Continence System is intended for use in women as a suburethral sling for the treatment of SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The GYNECARE TVT™ Obturator System is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT ABBREVO™ & GYNECARE TVT™ Obturator Implant. The Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT ABBREVO™ & GYNECARE TVT™ Obturator Implant Assembly.

The Winged Guide is a stainless steel accessory instrument that facilitates consistent passage of the GYNECARE TVT ABBREVO™ & GYNECARE TVT™ Obturator Implant Assembly through the dissection tract.

Comparison of Indication for Use and Technological Characteristics

Device & Predicate Device(s):	K181151	K100936 (TVT Abbrevo)	K033568 (TVT Obturator)
General Device Characteristics			
Indication for Use	The GYNECARE TVT ABBREVO™ Helical Passers and Atraumatic Winged Guide are intended to aid in the placement of the GYNECARE TVT ABBREVO™ device. The GYNECARE TVT™ Obturator Helical Passers and Atraumatic Winged Guide are intended to aid in the placement of the GYNECARE TVT™ Obturator device.	The GYNECARE TVT ABBREVO™ Continence System is intended for use in women as a suburethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.	The GYNECARE TVT Obturator device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
Operating principle	Aid in the placement of surgical mesh	Treatment of women with stress urinary incontinence	Treatment of women with stress urinary incontinence
Patient contact durations	< 24 hours (tissue/bone)	Permanent (tissue/bone)	Permanent (tissue/bone)
Device Design	Instrumentation	Mesh	Mesh
Device Materials	Stainless steel, polycarbonate	Woven polypropylene	Woven polypropylene

The indications for use statements for the subject device and the predicate device are not identical, as the predicate device is a surgical mesh that is indicated for stress urinary incontinence. The intended use of the subject and predicate device is the same, as the subject device is an accessory to a 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
- 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, and have a validated shelf life.

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.