September 17, 2020

Ethicon, Inc.
Ariell Joiner
Regulatory Affairs Specialist III
Route 22 West
Somerville, NJ 08876-0151

Re: K201686
Trade/Device Name: GYNECARE TVT™ System, GYNECARE TVT™ with Abdominal Guides System, GYNECARE TVT™ Introducer and Catheter Guide, GYNECARE TVT EXACT™ Continence System and Trocar, GYNECARE TVT™ Obturator System and Passers and Winged Guide, GYNECARE TVT ABBREVO™ Continence System and Passers and Winged Guide
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTN, PWJ
Dated: June 19, 2020
Received: June 22, 2020

Dear Ariell Joiner:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews
Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201686

Device Name
GYNECARE TVT™ System, GYNECARE TVT™ with Abdominal Guides System, GYNECARE TVT™ Introducer and Catheter Guide, GYNECARE TVT EXACT™ Continence System and Trocar, GYNECARE TVT™ Obturator System and Passers and Winged Guide, GYNECARE TVT ABBREVO™ Continence System and Passers and Winged Guide

Indications for Use *(Describe)*
The GYNECARE TVT Device is intended to be used as a pubo-urethral sling for treatment of Stress Urinary Incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT Introducer and Rigid Catheter Guide are available separately and are intended to facilitate in the placement of the GYNECARE TVT Device.

The GYNECARE TVT Device is intended to be used as a pubo-urethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT Introducer and Rigid Catheter Guide are available separately and GYNECARE TVT Abdominal Guides and Couplers are included in each kit.

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

The GYNECARE TVT 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 GYNECARE TVT EXACT Continence System is intended to be used as a pubo-urethral sling for treatment of female Stress Urinary Incontinence, resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The GYNECARE TVT EXACT Continence System Trocar is a single use device intended to aid in the placement of the GYNECARE TVT EXACT Continence System retropubically.

The GYNECARE TVT 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 EXACT Continence System.

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.

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 sub-urethral sling for the treatment of SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The GYNECARE TVT ABBREVO Helical Passers and Atraumatic Winged Guide are intended to aid in the placement of the GYNECARE TVT ABBREVO 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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510(k) Summary

Submitter: Ethicon, Inc. a Johnson & Johnson company
P.O. Box 151
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Somerville, NJ 08876-0151

Contact Person: Ariell Joiner
Regulatory Affairs Specialist
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Date Prepared: September 16, 2020

Urogynecologic Surgical Mesh Systems and Surgical Instruments

Device Trade Name:	GYNECARE TVT™ System GYNECARE TVT™ with Abdominal Guides System GYNECARE TVT™ Introducer and Catheter Guide GYNECARE TVT EXACT™ Continence System and Trocar GYNECARE TVT™ Obturator System and Passers and Winged Guide GYNECARE TVT ABBREVO™ Continence System and Passers and Winged Guide
Device Common Name:	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator Instrumentation, Surgical Mesh, Urogynecologic, Stress Urinary Incontinence
Class:	II
Classification:	21 CFR 878.3300 – Surgical mesh
Product Code:	OTN and PWJ
Panel:	General and Plastic Surgery Devices

Predicate Devices:

Device	Meshes		Instruments	
	Product Code	**510(k)**	**Product Code**	**510(k)**
GYNECARE TVT™ Tension-free Vaginal Tape (TVT System)	OTN	K012628	PWJ	K173019
GYNECARE TVT™ Reusable Introducer	Not Applicable (Reusable Instruments only)		PWJ	K173019
			PWJ	K173162

Device	Meshes		Instruments	
	Product Code	510(k)	Product Code	510(k)
GYNECARE TVT™ Reusable Rigid Catheter Guide	Not Applicable (Reusable Instruments only)		PWJ	K173019
			PWJ	K173162
GYNECARE TVT™ with Abdominal Guides Tension-Free Support for Incontinence System	OTN	K012628	PWJ	K173162
GYNECARE TVT EXACT™ Continence System	OTN	K132054	PWJ	K173019
GYNECARE TVT™ Obturator System	OTN	K033568	PWJ	K181151
GYNECARE TVT ABBREVO™ Continence System	OTN	K100936	PWJ	K181151

Device Description:

GYNECARE TVT™ Tension-free Vaginal Tape System

GYNECARE TVT™ Device is a sterile single use device, consisting of one piece of undyed or blue (up to 0.28 weight percent phthalocyanine blue, Color Index number 74160) PROLENE™ Polypropylene Mesh (tape) approximately 1/2 inch x 18 inches (1.1 cm x 45 cm), covered by clear plastic Sheaths overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.

PROLENE Polypropylene Mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE™ Polypropylene Nonabsorbable Surgical Sutures. The mesh is approximately 0.027 inches (0.7 mm) thick. PROLENE Mesh is knitted by a process which interlinks each fiber junction.

GYNECARE TVT™ Reusable Introducer (available separately) 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™ Rigid Catheter Guide (available separately) is a non-sterile reusable stainless-steel instrument intended to facilitate the identification of the urethra and the bladder neck during the placement of the GYNECARE TVT Device and the GYNECARE TVT EXACT Continence System. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra.

GYNECARE TVT™ with Abdominal Guides Tension-free Support for Incontinence System

GYNECARE TVT™ Abdominal Guide is a sterile disposable instrument intended to facilitate the passage of the GYNECARE TVT Device. Two Abdominal Guides are included in each kit with the GYNECARE TVT Couplers.

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.

GYNECARE TVT EXACT™ Continence System

GYNECARE TVT EXACT™ Continence System is a sterile, single patient use procedure kit consisting of:

A. GYNECARE TVT EXACT Continence System Trocar Sheath / Implant Assembly

The GYNECARE TVT EXACT™ Continence System Trocar Sheath / Implant Assembly consists of one piece of blue (up to 0.28 weight percent phthalocyanine blue, Color Index number 74160) PROLENE™ Polypropylene Mesh (Implant) approximately 1/2 inch x 18 inches (1.1 cm x 45 cm), covered by clear plastic Sheaths and overlapping in the middle, and held between two white Trocar Sheaths, which are bonded to the Implant and Implant Sheath. PROLENE Propylene Mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE™ Polypropylene Nonabsorbable Surgical Sutures. The Implant is approximately 0.027 inches (0.7 mm) thick. PROLENE Mesh is knitted by a process which interlinks each fiber junction.

B. GYNECARE TVT EXACT Continence System Trocar

The **GYNECARE TVT EXACT™ Continence System Trocar** consists of the stainless-steel Trocar Shaft and the plastic Trocar Handle. The Trocar Shaft is designed to fit inside the white Trocar Sheaths on the GYNECARE TVT EXACT™ Continence System Implant / Trocar Sheath Assembly and is used to position the GYNECARE TVT EXACT Continence System Implant in the patient, from a vaginal incision up through the abdominal wall.

GYNECARE TVT™ Obturator System

The **GYNECARE TVT™ Obturator System** is a sterile, single patient use procedure kit consisting

of:

A. GYNECARE TVT Obturator Device

The GYNECARE TV Obturator Device consisting of one piece of undyed or blue (up to 0.28 weight percent phthalocyanine blue, Color Index 74160) PROLENE™ polypropylene mesh (tape) approximately 1/2 inch x 18 inches (1.1 cm x 45 cm), covered by clear plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end.

PROLENE Propylene Mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE Polypropylene Non-absorbable Surgical Suture. The implant is approximately 0.027 inches (0.7 mm) thick.

B. GYNECARE TVT™ Obturator Helical Passers and Atraumatic Winged Guide

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

GYNECARE TVT™ Obturator Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

GYNECARE TVT ABBREVO™ Continence System

GYNECARE TVT ABBREVO™ Continence System is a sterile, single-patient use procedure kit consisting of:

A. GYNECARE TVT ABBREVO Implant Assembly

The GYNECARE TVT ABBREVO Implant Assembly consists of one piece of blue (up to 0.28 weight percent phthalocyanine blue, Color Index number 74160) PROLENE™ Polypropylene Mesh (Implant), approximately 1/2 inch x 4.7 inches (1.1 cm x 12 cm), covered by clear plastic Sheaths and held between two Helical Passer Sheaths (white polyethylene tube receptacles). The Helical Passer Sheaths are bonded to the mesh implant sheaths and the Positioning Lines (PROLENE™ Polypropylene Monofilament). PROLENE Mesh is constructed of knitted monofilaments of extruded polypropylene, identical in composition to that used in PROLENE™ Polypropylene Nonabsorbable Surgical Sutures. The Implant is approximately 0.027 inches (0.7 mm) thick.

B. GYNECARE TVT ABBREVO Placement Loop

The GYNECARE TVT ABBREVO Placement Loop is a sterile, single-patient use device consisting of a loop of PROLENE Polypropylene Monofilament with an attached polypropylene button. This loop and button are pre-assembled as part of the GYNECARE TVT ABBREVO Implant Assembly at the center of the mesh to aid in symmetric placement of the mesh.

C. GYNECARE TVT ABBREVO™ Helical Passers and Atraumatic Winged Guide

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

GYNECARE TVT ABBREVO™ Atraumatic Winged Guide is a stainless steel accessory instrument which facilitates consistent passage of the GYNECARE TVT ABBREVO Helical Passers through the dissection tract. The Winged Guide is marked with an Insertion Zone to aid the surgeon's assessment of inserted depth. The Insertion Zone indicates a distance of 3 cm to 4 cm from the tip of the Winged Guide.

Indications for Use:

The GYNECARE TVT Device is intended to be used as a pubo-urethral sling for treatment of Stress Urinary Incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT Introducer and Rigid Catheter Guide are available separately and are intended to facilitate in the placement of the GYNECARE TVT Device.

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

The GYNECARE TVT 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 Device is intended to be used as a pubo-urethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT Introducer and Rigid Catheter Guide are available separately and GYNECARE TVT Abdominal Guides and Couplers are included in each kit.

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 EXACT Continence System is intended to be used as a pubo-urethral sling for treatment of female Stress Urinary Incontinence, resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The GYNECARE TVT EXACT Continence System Trocar is a single use device intended to aid in the placement of the GYNECARE TVT EXACT Continence System retropubically.

The GYNECARE TVT 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 EXACT Continence System.

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.

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 sub-urethral sling for the treatment of SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The GYNECARE TVT ABBREVO Helical Passers and Atraumatic Winged Guide are intended to aid in the placement of the GYNECARE TVT ABBREVO Device.

The subject devices and their respective predicate devices have the same intended use.

Summary of Technological Characteristics:

The subject devices and their respective predicate devices are identical and therefore have the same technological characteristics.

Substantial Equivalence Discussion:

The subject devices differ from their respective predicate devices only in the labeling (Instructions for Use). The Instructions for Use of the subject devices have been revised to meet the new European Union (EU) Medical Device Regulation (MDR) requirements and include new sections to the Instructions or Use and clarifications throughout various existing sections of the Instructions for Use including additional warnings, adverse events, safety information, and information to be conveyed to patients. There are also minor clarifications to the Indications and Contraindications statements, and no changes to the single-use and reusable designations and patient populations**.** No performance data are needed to evaluate these labeling changes.

Conclusion:

Based on the intended use, fundamental scientific technology, and technological characteristics, the subject devices are substantially equivalent to their respective predicate devices.