April 9, 2021

Athena Surgical, LLC
% Kellen Hills
Biomedical Engineer
Medavise Consulting
8725 Columbine Rd. #44952
Eden Prairie, MN 55344

Re: K210087
Trade/Device Name: Athena Surgical RMUS System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTN
Dated: January 11, 2021
Received: January 13, 2021

Dear Kellen Hills:

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 -S

For
Jessica K. Nguyen, Ph.D.
Assistant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210087

Device Name
Athena Surgical RMUS System

Indications for Use *(Describe)*
The Athena Surgical RMUS System is indicated for use as a pubourethral sling for treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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

[As Required by 21 CFR 807.92]

(a)(1) Date Prepared:	January 11, 2021
Submitted By:	Athena Surgical, LLC 6110 Blue Circle Drive, Suite 280 Minnetonka, MN 55343
Phone:	612.888.9394
Contact:	Greg Slusser
Prepared By:	Medavise, LLC 8725 Columbine Rd. #44952 Eden Prairie, MN 55344
Phone:	612.405.4059
(a)(2) Proprietary Name:	Athena Surgical RMUS System
Common Name:	Urinary sling
Classification Regulation:	21 CFR 878.3300 - Surgical Mesh
Class:	II
Product Code:	OTN - Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator
(a)(3) Predicate Devices:	
Primary:	Ethicon GYNECARE TVT EXACT™ (K132054);

*No predicate has been subject to a design related recall.

(a)(4) Device Description:

The Athena Surgical RMUS System consists of a sterile, single-use Retropubic Mid-Urethral Sling (RMUS) Implant Assembly and a non-sterile, reusable RMUS Handle Assembly. Each RMUS Implant Assembly contains one blue polypropylene mesh sling implant (1.1cm x 46cm), covered by a non-implantable clear plastic sheath and attached on each end to non-implantable stainless steel needles. The mesh implant is constructed of knitted filaments of extruded polypropylene strands and is approximately 0.63mm thick.

The Athena Surgical RMUS Implant Assembly is designed to be used with the non-sterile, reusable Athena Surgical RMUS Handle Assembly, which consists of two parts: the Handle Body and the Handle Insert. The stainless steel needles from the RMUS Implant Assembly

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are designed to fit inside the RMUS Handle Assembly, which is used to position the implantable mesh in the patient from a vaginal incision up through the abdominal wall.

The purpose of this submission is to gain initial marketing authorization in the United States.

(a)(5) Indications for Use:

The Athena Surgical RMUS System is indicated for use as a pubourethral sling for treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(a)(6) Comparison of Technological Characteristics:

The Athena Surgical RMUS System is substantially equivalent to the identified predicate based on similarities in intended use, design, materials, sterilization and performance. The technological characteristics do not raise any new questions of safety and efficacy.

	Subject Athena Surgical RMUS System	Predicate Ethicon GYNECARE TVT EXACT™
510(k)	TBD	K132054
Regulation and Product Code	21 CFR 878.3300 - OTN	Same
Intended Use	The Athena Surgical RMUS System is intended to treat female stress urinary incontinence.	Same
Indications	The Athena Surgical RMUS System is indicated for use as a pubourethral sling for treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.	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.
Materials	Mesh – Polypropylene Sheath - Low Density Polyethylene Needle – Stainless Steel	Same
Delivery System Design	Handle with detachable curved Needle	Handle with fixed curved Needle
Entry Method	Transvaginal Retropubic	Same
Sterility	EtO, SAL 10^{-6}, single-use	Same
Performance	Ultimate Tensile Strength Elongation at Break Stiffness Bending Length	Same

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(b)(1) Non-clinical testing:

The subject device was successfully evaluated according to the following:

- Mechanical performance testing
  - Ultimate tensile strength
  - Elongation at break
  - Stiffness bending strength
  - Burst strength
  - Dimensional analysis (monofilament diameter, device width, pore size, mesh thickness, mesh density, mesh weave characteristics)
- Sterilization validation per ISO 11135:2014
- Reprocessing validation for reusable instrumentation
- Shelf life testing evaluating packaging integrity and mechanical performance
- Biocompatibility per ISO 10993-1
  - Implant Sheath and Needles (external communicating device contacting tissue for less than 24 hours)
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Acute systemic toxicity
  - Mesh (permanent implant contacting tissue for greater than 30 days)
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Acute systemic toxicity
    - Implantation
    - Subacute toxicity, subchronic toxicity, genotoxicity, and carcinogenicity through chemical characterization and toxicological risk assessment
- Pyrogenicity testing

(b)(2) Clinical testing:

Clinical testing was not required to demonstrate substantial equivalence in this premarket notification.

(b)(3) Conclusions:

Based on the information provided in this premarket notification the subject Athena Surgical RMUS System demonstrates substantial equivalence to the identified predicate device.