September 2, 2022

MSi
Greg Dumanian
Medical Officer
One Magnificent Mile
980 N. Lake Shore Drive, Suite 1400
Chicago, Illinois 60611

Re: K211178
Trade/Device Name: DURAMESH™ Mesh Suture
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW
Dated: April 19, 2022
Received: April 20, 2022

Dear Greg Dumanian:

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,

for Deborah Fellhauer, RN, BSN, CQIA
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K211178

Device Name
Duramesh™ Mesh Suture

Indications for Use *(Describe)*
Duramesh™ Mesh Suture is indicated for general soft tissue approximation and/or ligation in clean (CDC Class I) wounds, including tendon repair and midline laparotomy where the bowel is not entered. Duramesh™ is not for use in the skin and other epithelial surfaces, cardiovascular, ophthalmic, and/or neurological procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Contact Details

Applicant Name	MSi
Applicant Address	One Magnificent Mile 980 N. Michigan Ave. Suite 1400 Chicago, IL 60611 United States of America
Applicant Contact Telephone	202 737 9633
Applicant Contact	Jeffrey Shapiro
Applicant Contact Email	JShapiro@hpm.com
Date Prepared	September 2, 2022

Device Name

Device Trade Name	Duramesh™ Mesh Suture
Common Name	Surgical Suture
Classification Name	Suture, Nonabsorbable, Synthetic, Polypropylene
Regulation Number	878.5010
Product Code	GAW

Legally Marketed Predicate Device

Predicate #	*Predicate Trade Name*
K131224	Sharpoint™ polypropylene suture

Indications for Use

DURAMESH™ Mesh Suture is indicated for general soft tissue approximation and/or ligation in clean (CDC Class I) wounds, including tendon repair and midline laparotomy where the bowel is not entered. DURAMESH™ is not for use in the skin and other epithelial surfaces, cardiovascular, ophthalmic, and/or neurological procedures.

Device Description

DURAMESH™ is a polyfilament, synthetic, non-absorbable, sterile surgical suture composed of isotactic polypropylene polymer of high molecular weight. The suture is provided dyed (blue) and is uniform in appearance. The blue dye pigment is Phthalocyaninato (2-) Copper. The product meets all requirements established by the United States Pharmacopeia (USP) for non-absorbable surgical suture, except for diameter.

DURAMESH™ is passed on either side of tissues using an attached swaged needle as an introducing agent and tied to itself with at least two knots composed of two throws each to maintain tension.

DURAMESH™ is supplied sterile and is available with two needle configurations (small and large) in four USP sizes (2-0 through 2), each with a length of approximately 36 inches (91 cm). Each box contains one DURAMESH™ housed in a Tyvek envelope within which the DURAMESH™ is packaged in a sterile protective medical grade tube fixed to a sterile card.

Intended Purpose

DURAMESH™ is a permanent implant intended for single use by surgeons for the purpose of approximating soft tissues such as muscle, tendons, ligaments, and fascia with the exception of epithelial tissues such as skin, bowel, viscera and bladder mucosa. DURAMESH™ is not to be used in the closure of skin and other epithelial tissues, in the treatment of pelvic organ prolapse and stress urethral incontinence, as a dural substitute in intracranial or spinal surgery, in the closure of infected or dirty CDC Class IV wounds, or when an allergy to polypropylene is present. DURAMESH™ is not designed to be removed.

Comparison Table

	Subject Device	Predicate Device (K131224)
Trade Name	DURAMESH™	Sharpoint™ polypropylene suture
Indications for use	DURAMESH™ Mesh Suture is indicated for general soft tissue approximation and/or ligation in clean (CDC Class I) wounds, including tendon repair and midline laparotomy where the bowel is not entered. DURAMESH™ is not for use in the skin and other epithelial surfaces, cardiovascular, ophthalmic, and/or neurological procedures.	Sharpoint™ polypropylene suture is indicated for general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Design, needle	Grade 470 surgical needle with standardized shapes and sizes	Grade 470 surgical needle with standardized shapes and sizes
Design, suture body	Polyfilament suture comprised of 12 to 18 polypropylene filaments loosely braided to form a hollow cylinder with outer wall 1.5 mm to 4 mm in diameter. Diameter changes with lateral or axial tension.	Monofilament suture with filament diameter ranging from 0.03 mm to 0.5 mm. Diameter does not change with lateral or axial tension
Natural / Synthetic	Synthetic	Synthetic

Material	Isotactic polypropylene polymer of high molecular weight, Phthalocyaninato (2-) Copper	Isotactic polypropylene polymer of high molecular weight, Phthalocyaninato (2-) Copper
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Available Size Range	USP 2-0 through 2 (oversized)	USP 10-0 through 1
Specifications and Properties	Each size exceeds USP minimums for knot-pull tensometry (USP <881>) and needle attachment tensometry (USP <871>). Does not follow USP for diameter (USP <861>); the suture is oversized in diameter.	Each size exceeds USP minimums for knot-pull tensometry (USP <881>) and needle attachment tensometry (USP <871>). Does not follow USP for diameter (USP <861>)
Principle of Operation	The implant is threaded through two or more separated tissues with the aid of a surgical needle driver. The surgical needle pierces the tissue to allow the trailing suture body to be threaded. The surgeon applies axial tension on the implant thereby approximating the separated tissues. Tension is maintained with a self-holding knot created by the surgeon.	The implant is threaded through two or more separated tissues with the aid of a surgical needle driver. The surgical needle pierces the tissue to allow the trailing suture body to be threaded. The surgeon applies axial tension on the implant thereby approximating the separated tissues. Tension is maintained with a self-holding knot created by the surgeon.
Absorption / residual strength profile	Polypropylene suture is not absorbed, nor is there any significant change in tensile strength retention known to occur in vivo.	Polypropylene suture is not absorbed, nor is there any significant change in tensile strength retention known to occur in vivo.

DURAMESH™ has the same principles of operation as its predicate device and achieves soft tissue approximation and/or ligation with substantial equivalence to its predicate. Like its predicate, DURAMESH™ is introduced through tissues with an attached needle in order to achieve soft tissue approximation and/or ligation. Like its predicate, DURAMESH™ is tied with self-holding knots to maintain the required tension for tissue approximation. DURAMESH™ is made of polypropylene and is identical to the predicate in its synthetic material of fabrication and material chemical composition. Both DURAMESH™ and its predicate are sterilized with Ethylene Oxide, are not absorbed, and have no known significant changes in tensile strength occurring in vivo. The DURAMESH™ Indications for use specify use in clean wounds and exclude use in the skin and other epithelial surfaces, cardiovascular, ophthalmic, and/or neurological procedures while the predicate indications for use do not. DURAMESH™ differs from its predicate device in its design: it is a polyfilament mesh suture composed of multiple braided predicate filaments separated by air, while its predicate is a solid monofilament suture. The DURAMESH™ outer diameter is oversized compared to the predicate's, and changes with axial or lateral tension while the predicate diameter does not change. DURAMESH™ is available in USP sizes 2-0 through 2 with oversized outer diameters while the predicate is available in USP sizes 10-0 through 1 and has USP <861> - compliant outer diameters.

Non-Clinical Data

Biocompatibility

A biological risk assessment of DURAMESH™ was performed according to the requirements of the current ISO 10993-1, ISO 14971, and the 2020 FDA Biocompatibility Guidance. Based on cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, rabbit pyrogen,

genotoxicity, muscle implantation, and chemical characterization studies, DURAMESH™ was shown to be biocompatible per ISO 10993-1 for use as intended.

Packaging

Transport testing for DURAMESH™ in the final packaging and shipping configuration was conducted according to ASTM D4169-16, standard practice for performance testing of shipping containers and systems. Protection of the primary container (sterility) was confirmed via ASTM F1929 - 15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

Sterilization

DURAMESH™ is sterilized with Ethylene Oxide following AAMI TIR28:2016 guidelines [Product Adoption And Process Equivalence For Ethylene Oxide Sterilization]. The adoption standard augments ISO 11135:2014 [Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices]. DURAMESH™ meets the ISO 10993-7: 2008 limits for residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) for implanted devices.

Shelf-Life

Accelerated and real-time aging stability testing was completed to support a 5-year shelf for DURAMESH™. Data support no loss of tensile strength over the proposed shelf life.

Bench Data

DURAMESH™ passes prospectively defined acceptance criteria for needle attachment strength and tensile strength per FDA-recognized consensus standards USP43-NF38: 2020 <871> Sutures – Needle Attachment and USP43-NF38: 2020 <881> Sutures – Tensile Strength, respectively. DURAMESH™ diameter decreases with increasing axial load per Diameter vs. Load attribute testing. In Knot Size and Knot Strength testing, DURAMESH™ knots were shown to be stronger than predicate knots for the same number of throws. Testing shows that DURAMESH™ knot security is achieved with 4 throws as recommended in DURAMESH™ labeling. DURAMESH™ passes prospectively defined acceptance criteria for tensile strength, per USP requirements, under three separate loading conditions: simulated surgical deployment, cycle loading, and dynamic loading. An internal company study demonstrated that "stripped" samples of DURAMESH™ (with a loss of bonds between filaments) maintain adequate tensile strength to satisfy USP requirements.

Animal Data

Two large-animal porcine implantation studies for midline incision closure of 1- and 3-month durations were performed with endpoints of adverse tissue reaction (manifesting as excessive fibrosis, bowel adhesions, and infection) and dehiscence. In the 1- month and 3-month porcine studies, DURAMESH™ was able to close a midline incision with either a running or interrupted

suturing technique. DURAMESH™ exhibited tissue ingrowth and implant incorporation and was a slight irritant in comparison to standard polypropylene suture on semi-quantitative histology.

Clinical Data

Implantation of DURAMESH™ was performed in a single-investigator clinical trial of 53 patients with 80 individual surgery sites treated with DURAMESH™. The primary outcome was surgical site occurrence (SSO). Secondary outcomes included subject device related rehospitalization and return to the operating room, and wounds for any reason.

Fifteen of the total 53 DURAMESH™ subjects were brought back for a long-term assessment (12-month) of healing, function, pain, and quality of life. The remaining 38 subjects did not have evaluation at the 12-month endpoint. The 15 subjects were compared to a cohort of 11 patients who underwent similar orthopedic procedures for cerebral palsy with standard sutures.

The primary outcome showed no early or late SSO. Secondary outcomes showed no DURAMESH™ related rehospitalization or return to the operating room, and no wounds for any reason. One-year cohort comparison of DURAMESH™ to non-DURAMESH™ patients demonstrated equivalent or slightly improved outcomes with DURAMESH™.

Conclusion

All data and information lead to the conclusion that, despite the technological difference of polyfilament mesh suture versus monofilament suture design, DURAMESH™ is substantially equivalent to the predicate device for the proposed indications for use.