March 31, 2022

Antarma LLC dba Golnit Sutures
Armine Badalyan
CEO
276 5th Ave., Suite 704
New York, New York 10001

Re: K212888
Trade/Device Name: Golnit Nylon Monofilament Suture
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable Polyamide Surgical Suture
Regulatory Class: Class II
Product Code: GAR
Dated: September 9, 2021
Received: September 10, 2021

Dear Armine Badalyan:

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
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)*
K212888

Device Name
Golnit Nylon Monofilament Suture

Indications for Use *(Describe)*
The Golnit Nylon Monofilament Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular 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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510(k) Summary

In accordance with 21 CFR 807.92, the following summary of information is provided.

I. SUBMITTER

Name:	Antarma LLC dba Golnit Sutures
Address:	276 5th Avenue, Suite 704 New York, NY 10001
Phone:	718-219-0731
Contact Person:	Armine Badalyan, Chief Executive Officer
Date Summary Prepared:	February 25, 2022

II. DEVICE

Proprietary Name:	Golnit Nylon Monofilament Suture
Common Name:	Nonabsorbable polyamide surgical suture
Classification Name:	Suture, Nonabsorbable, Synthetic, Polyamide
Regulation:	21 CFR 878.5020
Regulatory Class:	II
Product Code:	GAR
Panel:	Surgical and Infection Control Devices (OHT4) / Infection Control and Plastic Surgery Devices (DHT4B)

III. PREDICATE DEVICE

The Golnit Nylon Monofilament Suture is being compared to the predicate device, REXLON, which was cleared under K161633 and manufactured by SM ENG CO., Ltd.

One reference device, the Golnit Non-Absorbable PTFE Surgical Suture, was used to support equivalence of the needle component and to support adoption into the product family for sterilization validation. The reference device was cleared under K163049.

Neither the predicate device nor the reference device has been the subject to a design-related recall.

IV. DEVICE DESCRIPTIONS

The Golnit Nylon Monofilament Suture is a synthetic monofilament nonabsorbable sterile surgical suture composed of the long-chain aliphatic polymers Nylon 6,6. The suture is pigmented black (logwood extract) or blue (FD&C Blue No. 2) to enhance visibility or is also available undyed (clear).

The suture has been designed to meet the requirements of the United States Pharmacopeia (USP) related to diameter, needle attachment and tensile strength. The suture is supplied sterile and is provided according to customer specifications. The device is available in pre-cut lengths from 10 cm

to 300 cm in 5 cm intervals and in USP sizes 10-0 through 2. It can be attached to a stainless-steel needle or be without a needle. Needles are available with various tip shapes (taper, cutting, reverse-cutting, taper-cutting, spatula, and diamond), curvatures (1/2, 3/8, 5/8, ¼ or straight) and lengths (4 mm to 70 mm).

Each suture is packaged into a labelled two-pouch packaging system consisting of medical grade heat-sealable pouches. The suture is sterilized by ethylene oxide and is intended for single use only.

V. INTENDED USE / INDICATIONS FOR USE

The Golnit Nylon Monofilament Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neurological procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

Attribute	Proposed Device – Golnit Nylon Monofilament Suture	Predicate Device – REXLON	Reference Device – Golnit Non-Absorbable PTFE Surgical Suture
Product Code	GAR	GAR	NBY
Regulation	21 CFR 878.5020	21 CFR 878.5020	21 CFR 878.5035
Intended use	Soft tissue approximation and/or ligation	Soft tissue approximation and/or ligation	Soft tissue approximation and/or ligation
Indications for use	The Golnit Nylon Monofilament Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neurological procedures.	REXLON is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.	The GOLNIT Non-Absorbable PTFE Surgical Suture is indicated for use in all types of soft tissue approximation and/or ligation, including dental, cardiovascular and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue
How Supplied	Sterile monofilament thread in various colors and sizes with or without attached needles	Sterile monofilament thread in various colors and sizes with or without attached needles	Sterile monofilament thread in various sizes with or without attached needles
Suture Specifications			
Material	Polyamide surgical suture from long-chain aliphatic polymers Nylon 6 and Nylon 6,6	Polyamide surgical suture from long-chain aliphatic polymers Nylon 6 and Nylon 6,6	Polytetrafluoroethylene (ePTFE) polymer (100%), expanded and uncoated monofilaments
Color (colorant)	Undyed (natural) Black (Logwood extract)	Undyed (natural) Black (Logwood extract)	Natural (undyed)

Attribute	Proposed Device – Golnit Nylon Monofilament Suture	Predicate Device – REXLON	Reference Device – Golnit Non-Absorbable PTFE Surgical Suture
	Blue (FD&C Blue No. 2)	Blue (FD&C Blue No. 2)	
Coating	None	None	None
Nonabsorbable	Yes	Yes	Yes
Monofilament	Yes	Yes	Yes
Sizes	USP 10/0 to 2	Black: USP 11/0 to 1 Blue: USP 8/0 to USP 2 Undyed: USP 8/0 to USP 1	2-0 to 6-0
Length	10 cm to 300 cm with 5 cm intervals	15 cm, 20 cm, 30 cm, 35 cm, 40 cm, 45 cm, 50 cm, 60 cm, 70 cm, 75 cm, 80 cm, 100 cm, 150 cm, 200 cm	10 cm to 300 cm with 5 cm intervals
Needle			
Material	Stainless steel	Stainless steel	Stainless steel
Needle type	Taper, Cutting, Reverse-cutting, Taper-cutting (tapercut), Spatula, Diamond, no needle	Reverse cutting, Taper point, Spatula	Taper, Reverse Cutting, Taper-Cutting
Performance Characteristics and Safety			
Packaging	Dry packaged in tear-open double paper/PET/CPP pouches	Dry packaged in tear-open pouch	Dry packaged in tear-open double paper/PET/CPP pouches
Suture Diameter per USP <861>	Meets requirements	Meets requirements	Meets requirements
Suture Needle Attachment per USP <871>	Meets requirements	Meets requirements	Meets requirements
Tensile Strength per USP <881>	Meets requirements	Meets requirements	Meets requirements
Sterile	Yes	Yes	Yes
Method of Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Biocompatible	Yes	Yes	Yes

The Golnit Non-Absorbable PTFE Surgical Suture was used as a reference device to support equivalence of the needle component and to support adoption into the product family for sterilization. Both the reference device and proposed device use the same stainless-steel needle from the same supplier and have the same sterilization parameters. The proposed device may be supplied with additional needle tip shapes.

VII. PERFORMANCE DATA

No clinical or animal testing was conducted.

Testing that was performed demonstrate that the suture meets the requirements outlined in *Class II Special Controls Guidance: Surgical Sutures; Guidance for Industry and FDA; June 3, 2003*. Testing in accordance with to the USP monographs for non-absorbable sutures, including an evaluation of diameter, tensile strength, and needle attachment strength, was performed. This performance testing demonstrated that the Golnit Monofilament Suture meets the USP requirements for suture diameter, suture needle attachment, and tensile strength.

Real-time aging stability testing was performed to support shelf life of the Golnit Nylon Monofilament Suture, and this testing supported the shelf life of the device.

Biocompatibility testing was also performed per *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff*. This testing demonstrated that the device is biocompatible.

All testing demonstrated that the Golnit Nylon Monofilament Suture is as safe and effective as the predicate device.

VIII. CONCLUSIONS

Based on the performance data and comparison to the predicate device, the Golnit Nylon Monofilament Suture has been shown to be substantially equivalent to the legally marketed predicate device.