September 4, 2019

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

Re: K192088
Trade/Device Name: GOLNIT Non-aborbable PTFE Surgical Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: NBY
Dated: August 2, 2019
Received: August 5, 2019

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 Cindy Chowdhury
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192088

Device Name
GOLNIT Non-absorbable PTFE Surgical Suture

Indications for Use *(Describe)*
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.

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

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:	August 2, 2019

II. DEVICE

Proprietary Name:	GOLNIT Non-absorbable PTFE Surgical Suture
Common Name:	PTFE Surgical Suture
Classification Name:	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene
Regulation:	21 CFR 878.5035
Regulatory Class:	II
Product Code:	NBY
Panel:	Office of Product Evaluation and Quality / Office of Health Technology 4 (OHT 4) / Infection Control and Plastic and Reconstructive Surgery (DHT4B)

III. PREDICATE DEVICE

The predicate devices for this submission are Antarma's GOLNIT Non-absorbable PTFE Surgical Suture (K163049, primary predicate device), Osteogenics Biomedical, Inc.'s Cytoplast PTFE Suture (K072076, secondary predicate device), Foosin Medical Supplies Inc., Ltd's WEGO-PTFE Suture (K170842, third predicate device) and Dura Tap LLC's Gazelle PTFE Suture and Delivery Device (K173335, fourth predicate device). None of these predicates have been the subject to a design-related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The GOLNIT Non-absorbable PTFE Surgical Suture is a sterile, disposable, non-absorbable suture that meets the requirements of the United States Pharmacopeia (U.S.P.) except for diameter. The suture is manufactured of a 100% polytetrafluoroethylene (PTFE) polymer as monofilament strands that are uncoated, undyed, and of various diameters and lengths that may be crimped or swaged to a standard, medical grade suture needle. The suture sizes range from U.S.P. 2-0 to 6-0.

The surgical suture incorporates a monofilament manufactured from 100% virgin

polytetrafluoroethylene (PTFE) resin that is extruded as an expanded porous (ePTFE) monofilament that is soft and supple.

The final configuration of the GOLNIT Non-absorbable PTFE Surgical Suture consists of specified length and diameters of PTFE monofilaments with attached standard, medical grade suture needles. The suture is packaged into a labelled two-pouch packaging system consisting of medical grade heat-sealable pouches. The GOLNIT Non-absorbable PTFE Surgical Suture is sterilized by ethylene oxide and is intended for single use only.

V. INTENDED USE / INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There have been no design changes between the originally cleared GOLNIT Non-absorbable PTFE Surgical Suture device and the proposed device. Thus, the two GOLNIT devices have the same technological characteristics as there have been no changes to the design, manufacturing, sterilization or packaging of the device.

Additionally, the proposed GOLNIT Non-absorbable PTFE Surgical Suture has the same technological characteristics with the other predicate devices, including the material composition, color, suture sizes, suture length, needle material, packaging, and sterilization.

While the proposed Indications for Use differ between the initially cleared and proposed GOLNIT devices, the proposed Indications for Use is identical to the other predicate devices. The use of PTFE sutures in these expanded indications has been well-established and does not raise any new issues of safety and effectiveness.

VII. PERFORMANCE DATA

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,* additional biocompatibility testing was performed to demonstrate substantial equivalence to the predicate device. All testing demonstrated that the GOLNIT Non-absorbable PTFE Surgical Suture is as safe and effective as the predicate device.

VIII. CONCLUSIONS

Based on the performance data and comparison to the predicate devices, Antarma concludes that the GOLNIT Non-absorbable PTFE Surgical Suture has been shown to be substantially equivalent to the legally marketed predicate devices.