August 27, 2020

Aptos, LLC.
Nikolai Pirtskhalaichvili
Vice President of Operations
20/4 V. Orbeliani Street
Tbilisi, 0105 Ge

Re: K192953
Trade/Device Name: APTOS Threads - Polypropylene Surgical Sutures
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW
Dated: October 18, 2019
Received: October 21, 2019

Dear Nikolai Pirtskhalaichvili:

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,

Cindy Chowdhury, Ph.D., M.B.A.
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)*
K192953

Device Name
APTOS Threads – Polypropylene Surgical Sutures

Indications for Use *(Describe)*
The APTOS Threads – Polypropylene Surgical Sutures are indicated for general soft tissue approximation, excluding closure of the epidermis, where use of a non-absorbable suture is appropriate.

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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Submission Date: October 21, 2019

K192953

1. SUBMITTER

APTOS, LLC.
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2. DEVICE

Device Trade Name: APTOS Threads – Polypropylene Surgical Sutures
Common Name: Nonabsorbable polypropylene surgical suture
Classification Regulation: 21 CFR 878.5010
Regulatory Class: II
Product Code: GAW
Panel: General and Plastic Surgery

3. PREDICATE DEVICE

Predicate Device: FilBloc Permanent Sutures (K171039)

4. DEVICE DESCRIPTION

APTOS Threads - Polypropylene Surgical Sutures are a dyed, nonabsorbable, sterile surgical strand of polypropylene in USP size 2-0. The base product is an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin.

The pigmented suture is dyed blue (with [Phthalocyaninato(2-)] copper, Color Index Number 74160) to enhance visibility; the colorant meets all requirements of US 21CFR, Parts 70-82. There is no coating or any other additives.

The threads incorporate a bidirectional barbed design. The threads are supplied with needles attached to both ends. The thread's upper and lower anchoring sections are barbed in opposite direction with a small unbarbed section between them and two smooth unbarbed sections, each immediately adjacent to needle-thread attachment interfaces. The needles are constructed from 420B stainless steel. The needles are provided sterile via Ethylene Oxide sterilization.

5. INDICATIONS FOR USE

The APTOS Threads – Polypropylene Surgical Sutures are indicated for general soft tissue approximation, excluding closure of the epidermis, where use of a non-absorbable suture is appropriate.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The proposed device is a barbed suture device with very similar physical characteristics to the predicate. Both devices are constructed from polypropylene and possess barbs to achieve the intended use of approximation of tissue.

The FilBloc Permanent Suture device does have some differences, as it has a wider variety of designs and options, such as unidirectional barbs, non-barbed sutures. The proposed device configuration is the same design as one of the predicate configuration, i.e. size 2-0 sutures with bidirectional barbs.

The similarities and differences in technological characteristics between the subject APTOS Threads – Polypropylene Surgical Sutures and the predicate sutures are summarized below.

Device Comparison Table:

	Proposed New Device	**Predicate Device**
510(k) Number	K192953	K171039
Applicant	AMAP International, Inc.	Assut Europe, Italy
Device Name	APTOS Threads – Polypropylene Surgical Sutures	FilBloc Permanent Sutures
Classification Regulation	21 CFR 878.5010	21 CFR 878.5010
Product Code	GAW	GAW
Indication	Aptos Threads – Polypropylene Surgical Sutures are indicated for general soft tissue approximation, excluding closure of the epidermis, where use of a non-absorbable suture is appropriate.	FilBloc Permanent sutures are intended for general soft tissue approximation, excluding closure of the epidermis, where use of a non-absorbable suture is appropriate.

	Proposed New Device	**Predicate Device**
Design	APTOS Threads – Polypropylene Surgical Sutures incorporate a bidirectional barbed design. The threads are supplied with needles attached to both ends. The thread's upper and lower anchoring sections are barbed in opposite direction with a small unbarbed section between them and two smooth unbarbed sections, each immediately adjacent to needle-thread attachment interfaces. The needles are constructed from 420B stainless steel. Standard needle attachment.	Device Description: The Assut FilBloc Permanent Suture range of devices comprises a variety of gauge sizes and lengths, supplied with or without stainless steel needles, which are also available in a variety of different sizes and shapes. The sutures may have a 'block' at one end, which allows surgeons to close wounds quickly and securely without tying knots or changing suturing techniques. The block is made from the same material as the suture, and is used to anchor the suture. The suture thread can be smooth or can have unidirectional or bidirectional barbs along the axis of the monofilament surface, either convergent or divergent.
Rx Only?	Yes	Yes
Suture Barbs	Bi-Directional	None Bidirectional Unidirectional
Materials	Polypropylene Monofilament	Polypropylene Monofilament
Dyed	phthalocyanine copper - C.I. 74160; 21 CFR§ 74.3045	phthalocyanine copper - C.I. 74160; 21 CFR§ 74.3045
USP Sizes	USP 2-0	4/0 to 1
Needle Shape	Straight	1/2 circle, 3/8 circle, 5/8 circle, "ski" needle, Straight
Needle Cross Section	Cylindrical	Cylindrical, Triangular, Trapezoidal
Needle Material	420B stainless steel	Surgical stainless steel: AISI 470, AISI 455, AISI 301, AISI 302, AISI 304, AISI 304L, AISI 31,6 AISI 320, AISI 321, Cobalt chromium
Single Use	Yes	Yes
Sterile	Yes, EO Sterilization, SAL 10^{-6}	Yes, EO Sterilization, SAL 10^{-6}
Complies with USP<861>, USP<871>, USP<881>	Yes	Yes
Biocompatible	Biocompatible in accordance with ISO 10993-1 and FDA Guidance	Biocompatible in accordance with ISO 10993-1 and FDA Guidance

7. PERFORMANCE DATA

Biocompatibility

Biocompatibility testing was performed in accordance with ANSI/AAMI/ISO 10993-1:2009/(R)2013, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within A Risk Management Process, as well as FDA's 2016 guidance document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process." Specific testing included the following:

- Cytotoxicity, ISO 10993-5
- Sensitization, ISO 10993-10
- Irritation, ISO 10993-10
- Acute systemic Toxicity, ISO 10993-11
- Materials Mediated Pyrogenicity, ISO 10993-11
- Implantation, ISO 10993-6
- Hemocompatibility, ISO 10993-4, ASTM F756-17
- Subchronic Toxicity, 90-day Subchronic Intramuscular Implantation, ISO 10993-11
- Genotoxicity, Ames Bacterial Reverse Mutation Assay, OECD 471
- Genotoxicity: *In Vivo* Mouse Micronucleus Mutagenicity Assay, OECD 487
- Genotoxicity: Mouse Lymphoma Assay, OECD 476
- Bacterial Endotoxin Test, USP<161>

Bench Testing

Physical testing was performed to establish compliance with:

- USP<861> suture diameter
- USP<871> suture attachment
- USP<881> tensile strength

Ex-vivo tissue holding strength testing was conducted compared to the predicate to demonstrate substantially equivalent tissue holding strength.

Ethylene Oxide sterility validation testing was conducted in accordance with overkill half-cycle methods per ISO 11135:2014 to demonstrate SAL 10^{-6}. Residuals were evaluated in accordance with ANSI/AAMI/ISO 10993-7:2008/(R) 2012.

Shelf life testing involved package integrity and seal strength testing subsequent to environmental preconditioning and distribution simulation, in accordance with AAMI/ISO 11607-1: 2006 (R) 2010, ASTM D4169-16, ASTMF88/F88M-15, and ASTM F2096-11.

Animal Study

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Study

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSIONS

The technological features of the APTOS Threads – Polypropylene Surgical Sutures are very similar to the predicate device, as both devices are constructed of dyed polypropylene, and may have divergent bi-directional barbs, with smooth sections in the middle and next to the introductory needles. Testing was conducted to demonstrate that the APTOS Threads – Polypropylene Surgical Sutures are substantially equivalent to the predicates. This included testing to demonstrate that, like the predicates, the APTOS Threads are biocompatible, sterile, have adequate shelf life, meet USP physical testing requirements for sutures, and possess tissue holding strength adequate to approximate tissue. The results of this testing demonstrate that the APTOS Threads – Polypropylene Surgical Sutures are substantially equivalent to the predicate devices.