November 13, 2020

T.A.G. Medical Products Corporation, Ltd
Anat Rozen
RA Manager
Gaaton, Israel 2513000

Re: K202178
Trade/Device Name: Versaloop™ Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 8, 2020
Received: October 13, 2020

Dear Anat Rozen:

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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K202178

Device Name
VersaLoop™ Anchor System

Indications for Use *(Describe)*
The VersaLoop™ Anchor System is intended for use in soft tissue to bone fixation in the repair of the natural ligament or tendon disruption or to assist in reconstruction surgeries.
Specific indications are: foot, ankle, knee, hip, hand, wrist, elbow and shoulder.

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

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1.	**Submitter Address:**	Shlomi Dines T.A.G. Medical Products Corporation, Ltd. Gaaton 2513000, ISRAEL www.tag-med.com
	Mfg. Phone:	Tel.: 972-4-9858400
	Contact Person:	Anat Rozen
	Date:	November 13th, 2020
2.	**Device & Classification**	Suture Anchor, class II, 21 CFR 888.3040 Fastener, Fixation, Nondegradable, Soft Tissue, product code MBI
	Name:	VersaLoop™ Anchor System: VersaLoop ™ 1.5MM - SINGLE LOADED SUTURE VersaLoop ™ 1.5MM - SINGLE LOADED TAPE VersaLoop ™ 1.8MM - DOUBLE LOADED SUTURE VersaLoop ™ 1.8MM - DOUBLE LOADED TAPE VersaLoop ™ 2.5MM - DOUBLE LOADED SUTURE VersaLoop ™ 2.5MM - DOUBLE LOADED TAPE VersaLoop ™ 2.5MM - TRIPLE LOADED SUTURE
3.	**Predicate Devices:**	K113297 - KNOTILUS ANCHOR SYSTEM (primary predicate) K181769 - Arthrex FiberTak Suture Anchor
4.	**Reference Devices:**	K132043 - Arthrex SpeedCinch K193575 - Arthrex SutureTape
5.	**Description:**	The VersaLoop™ Anchor System consists of an inserter and Ultra High Molecular Weight Polyethylene (UHMWPE) non-absorbable loop suture anchor and threaded sutures. The inserter shaft ends with a "fork" tip which holds the suture anchor. There are 3 narrow slots on the handle which holds the suture, which can be press-locked and released. The handle is designed for hammering the inserter into the pilot hole to deploy the anchor. When the suture anchor is inserted into bone and the inserter is removed, the main sutures are pulled, and the all-suture anchor (loop) creates a “bunching” effect using targeted compression zones within the implant sheath for optimal fixation.
6.	**Intended Use:**	The VersaLoop™ Anchor System is intended for use in soft tissue to bone fixation in the repair of the natural ligament or tendon disruption or to assist in reconstruction surgeries. Specific indications are: foot, ankle, knee, hip, hand, wrist, elbow and shoulder.

7. Comparison of Technological Characteristics:

The VersaLoop™ Anchor System is substantially equivalent to the TAG Knotilus Anchor System (K113297) and to the Arthrex FiberTak Suture Anchor (K181769) in that it has the same intended use and features similar technology.

The Knotilus Anchor System (K113297), Arthrex FiberTak Suture Anchor (K181769) and the proposed VersaLoop™ Anchor System are intended for use in soft tissue to bone fixation in the repair of the natural ligament or tendon disruption or to assist in reconstruction surgeries. The clinical use is identical; both are anchor system devices. Additionally, both devices' designs allow for the devices to be endoscopically delivered from a single access point.

The differences in the technological characteristics; anchor material and dimensions, and inserter handle design, do not raise different questions of safety and effectiveness as demonstrated by performance and biocompatibility test data. The indications for use are identical and the subject device, the VersaLoop™ Anchor System, is as safe and effective as the predicate devices, the Knotilus Anchor System (K113297) and Arthrex FiberTak Suture Anchor (K181769).

The proposed VersaLoop™ Anchor System is substantially equivalent to the legally marketed Knotilus Anchor System(K113297) and the Arthrex FiberTak Suture Anchor (K181769).

Nonclinical test discussion:

Nonclinical testing was completed to demonstrate that the VersaLoop™ Anchor System devices meets the established performance characteristics, and to verify that design requirements are satisfied. Testing included biocompatibility evaluation per ISO 10993-1, ethylene oxide sterilization validation, and Bacterial Endotoxin (BET).

Device testing included dimensional, mechanical (fatigue testing, pullout testing, torque testing, applied forces testing) and functional testing.

FDA Guidance that was used for testing: "Bone Anchors - Premarket Notification (510(k)) Submissions Guidance for Industry and Food and Drug Administration Staff"

It was concluded from the nonclinical tests that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicate (21 CFR 807.92(b)(3)).