May 19, 2019

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

Re: K190125
Trade/Device Name: FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire®, FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire®
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 3, 2019
Received: April 8, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma and Restorative 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190125

Device Name
FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire®
FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire®

Indications for Use *(Describe)*
The FiberStitch™ Meniscal Repair Device is intended for use as a suture retention device to facilitate endoscopic soft tissue procedures.
The FiberStitch™ Meniscal Repair Device is indicated for use in meniscal repair 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.

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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:	April 03, 2019
2.	**Device & Classification Name:**	Suture Anchor, class II, 21 CFR 888.3040 Fastener, Fixation, Nondegradable, Soft Tissue, product code MBI FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire® FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire®
3.	**Predicate Devices:**	K121861- Smith & Nephew - ULTRA FAST-FIX Meniscal Repair System K111564- Biomet Sports Medicine - Maxfire Marxmen Meniscal Repair Device K132043- Arthrex Inc. - Arthrex SpeedCinch K943949- LOOK – Polyviolene Surgical Suture
4.	**Description:**	The FiberStitch™ devices are an all-inside meniscal repair device. The devices include two non-absorbable polyester implants, pre-tied with #2-0 non-absorbable sutures and preloaded into a needle delivery system. The adjustable depth penetration limiter is preset to approximately 18mm from the tip of the needle. It can be adjusted down in 2 (mm) increments to approximately 10mm.
5.	**Intended Use:**	The FiberStitch™ Meniscal Repair Device is intended for use as a suture retention device to facilitate endoscopic soft tissue procedures. The FiberStitch™ Meniscal Repair Device is indicated for use in meniscal repair procedures.
6.	**Comparison of Technological Characteristics:**	With respect to its indication for use, the FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire® and FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire® are substantially equivalent to its predicate devices in their design which allows for the devices to be endoscopically delivered from a single access point as the proposed FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire® and the FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire® devices. Sutures material is similar to Maxfire Marxmen Meniscal Repair Device. The clinical use is similar; devices are considered all-inside meniscal repair devices. Conversely, FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire® and the FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire® are different than their predicate devices in geometry and details of the operating mechanism while general dimensions are same. The deployment of the sutures in FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire® and the FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire® is accomplished by rotating the wheel while for the predicate

devices deployment of sutures is accomplished by pushing the dedicated trigger. Suture materials are different albeit they are biocompatible.

Nonclinical test discussion:

Nonclinical testing was completed to demonstrate that the FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire® and FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire® 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 package qualification. Device testing included surface/visual, dimensional, mechanical and functional testing. It was concluded that the FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire® and the FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire® are as safe and effective as the predicate devices.