September 7, 2022

T.A.G. Medical Products Corporation, Ltd
Shlomi Dines
RA/QA Director
Gaaton 2513000, ISRAEL

Re: K221731
Trade/Device Name: FiberStitch™ Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 10, 2022
Received: June 15, 2022

Dear Shlomi Dines:

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:

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)*

K221731

Device Name
FiberStitch™ Implant

Indications for Use *(Describe)*
The FiberStitch™ Implant is intended for use as a suture retention device to facilitate endoscopic soft tissue procedures. The FiberStitch™ Implant Device is indicated for use in rotator cuff and 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.

510(k) Summary

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

1.	**Submitter Address:**	T.A.G. Medical Products Corporation, Ltd. Gaaton 2513000, ISRAEL www.tag-med.com
	Mfg. Phone:	Tel.: 972-4-9858400
	Contact Person:	Shlomi Dines
	Date:	September 1, 2022
2.	**Device & Classification Name:**	Suture Anchor, class II, 21 CFR 888.3040 Fastener, Fixation, Nondegradable, Soft Tissue, product code MBI FiberStitch™ Implant
3.	**Predicate Device:**	K190125 FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire®, FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire®
4.	**Reference Device:**	K203117 TissueTak device
5.	**Indications for Use:**	The FiberStitch™ Implant is intended for use as a suture retention device to facilitate endoscopic soft tissue procedures. The FiberStitch™ Implant Device is indicated for use in rotator cuff and meniscal repair procedures.
6.	**Comparison of Technological Characteristics:**	In comparison to the predicate device, the FiberStitch™ Implant is identical in design, materials and methods of manufacturing, shelf life, sterilization and packaging. Bacterial endotoxin per USP <85>was conducted to demonstrate that the device meets pyrogen limit specifications. The proposed device is labeled with an additional indication, rotator cuff repair. In comparison to the absorbable reference predicate, the subject device is made of nondegradable polyester. The reference predicate is manufactured from PLGA8218. Both devices are indicated for rotator cuff repair. **Nonclinical testing discussion:** To mitigate the risks of usability and functionality of the device due to the additional indication of rotator cuff repair, validation via cadaveric evaluation and biomechanical tensile strength testing was performed on the subject and reference devices. Based on the testing conducted and comparison of technological characteristics and intended use, it is concluded that the FiberStitch™ Implant is as safe and effective as the predicate devices.