March 24, 2021

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

Re: K210498
Trade/Device Name: Betta Link™ Knotless Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 16, 2021
Received: February 22, 2021

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,

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)*
K210498

Device Name
Betta Link™ Knotless Anchor System

Indications for Use *(Describe)*
The Betta Link™ Knotless 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:	Mar 24th, 2021
2.	**Device & Classification**	Class II, 21 CFR 888.3040 Fastener, Fixation, Nondegradable, Soft Tissue, product code MBI
	Name:	Betta Link™ Knotless Anchor System: Betta Link SR Knotless Implant Only Betta Link LG Knotless Implant Only
3.	**Predicate Devices:**	K113297 - KNOTILUS ANCHOR SYSTEM K122314 - Quattro™ Link Knotless Anchor
4.	**Reference Devices:**	K190125 - FiberStitch Implant, Curved With Two Polyester Implants And 2-0 FiberWire, FiberStitch Implant, Straight With Two Polyester Implants And 2-0 FiberWire
5.	**Description:**	The Betta Link™ Knotless Anchor System consists of an inserter and PEEK (Polyether-ether-ketone) non-absorbable anchor. The device is a manual surgical device and is comprised of a handle and PEEK anchor on a proximal (to user) edge of the inserter shaft. The inserter shaft ends with a dedicated "fork" tip which holds the anchor. The handle is designed for hammering the inserter into the pilot hole to deploy the anchor. When the anchor is inserted into bone and the inserter is removed the fixation is achieved.
6.	**Intended Use:**	The Betta Link™ Knotless 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 Betta Link™ Knotless Anchor System is substantially equivalent to the TAG Knotilus Anchor System (K113297) in that it has the same intended use, same anchor material and features similar technology. Both the Knotilus Anchor System (K113297) and the proposed Betta Link™ Knotless 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 difference in the technological characteristics; inserter handle design, do not raise different questions of safety and effectiveness as demonstrated by performance test data. The indications for use are identical and the subject device, the Betta Link™ Knotless Anchor System, is as safe and effective as the predicate device, the Knotilus Anchor System (K113297).

The proposed Betta Link™ Knotless Anchor System is substantially equivalent to the legally marketed Knotilus Anchor System (K113297).

Nonclinical test discussion:

Nonclinical testing was completed to demonstrate that the Betta Link™ Knotless 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)).