January 23, 2025

OTS Medical Ltd.
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K241234
Trade/Device Name: OTS 25-L
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 2, 2024
Received: December 26, 2024

Dear Janice Hogan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferriera, MS
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
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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)*
K241234

Device Name
OTS 25-L

Indications for Use *(Describe)*

The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The OTS 25-L All-Suture Anchors may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, both may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor system stabilizes the damaged soft tissue.

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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K241234

510(K) SUMMARY

OTS Medical Ltd.'s OTS 25-L

Submitter

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Phone: +972-54-6171726

Contact Person: Dr. Assaf Dekel

Date Prepared: January 14, 2025

Name of Device: OTS 25-L

Common or Usual Name: Smooth or threaded metallic bone fixation fastener

Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue

Regulation Number: 888.3040

Product Code: MBI

Predicate Devices

- K233429 – OTS 25, MBI
- K133224 Y-Knot All-Suture Anchor, MBI

Device Description

TS 25-L is an all-suture anchor. It is a soft-tissue fixation device with an expandable push-in design, provided preloaded on a disposable inserter. The device is constructed of a flat suture sleeve that is interlaced longitudinally along its central width by two #2 suture strands. The flat suture sleeve and the double loaded suture strands are folded back on themselves at the distal end of the disposable inserter. The device consists of the following components and accessories: non-absorbable, single use, suture anchor is made of a braided polyester sleeve; inserter; drill bit; and drill guide are made of stainless steel; and drill guide obturator is made of polypropylene.

The disposable inserter has a stainless-steel shaft supporting a forked shaped tip, with a handle, and is provided sterile, for single use.

Intended Use / Indications for Use

The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.

The OTS 25-L All-Suture Anchors may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, both may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor system stabilizes the damaged soft tissue.

Indications for Use Comparison

The OTS 25-L has the exact same intended use of its predicate devices the OTS 25 (K233429) and ConMed's Y-Knot® RC All-Suture Anchor with two or three #2 Hi-Fi® Sutures (K133224). Namely, all three devices are intended to reattach soft tissue to bone in orthopedic surgical procedures. The indications for use of the three devices are identical aside from differences in device name.

All three all-suture anchors may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, all three may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules, to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor systems stabilize the damaged soft tissue.

In other words, the OTS 25-L has the same exact intended use and indication for use as its predicate devices. Thus, the OTS 25-L satisfies the first criterion for a finding of substantial equivalence.

Technological Comparison

The OTS 25-L and predicate device have bone anchoring and soft tissue attachment elements. All three devices are made from a flat suture/flat sleeve structure that bunches during deployment, providing the same bone fixation method between the anchors. Specifically, the subject device and its predicates use a suture-only anchor mechanism where fixation to the bone is achieved by changes to the shape of the suture within the soft cancellous bone when the sutures are tightened, preventing it from being pulled through the pilot hole in the hard bone.

The OTS 25-L and the predicates' anchors also share the same soft tissue attachment method, i.e., suture attachment. Both use #2 sized UHMWPE sutures, with two sutures being supplied with OTS device while two or three sutures are provided with the predicate. As use of two sutures is a subset of the predicate, it does not raise any questions.

The OTS 25-L suture anchor is inserted through a predrilled hole and therefore have the same insertion mechanism as its predicates OTS 25 (K233429) and Y knot RC by Conmed (K133224). The fork-shaped inserter, drill bit, and the drill bit guide used to insert the device are similar to the predicates' instruments as well, resulting in an equivalent, 8-step insertion method as its predicate.

The main difference between the OTS 25-L and its predicates is the extension at the distal part of the anchor. This extension is placed on top of the tendon, similar to other all-suture anchors which have a tape rather than a suture – e.g., Y-Knot PRO RC with Hi Fi Tape in that it is intended to reduce the risk of suture cut through by spreading the force the suture applies to the tendon across a greater area.

Performance Data

OTS 25-L was tested for insertion, pullout, as well as for cyclic loading, on bone substitute and compared to the predicate devices, in order to demonstrate equivalence in performance.

Concentration of sterilization residuals and bioburden testing was performed the device remained within acceptable limits.

As there were no new materials or manufacturing methods, no new biocompatibility testing was performed.

Following nonclinical tests, it was concluded that OTS 25-L is as safe, as effective, and performs at least as well as the legally marketed predicate devices.

Conclusions

The OTS 25-L is as safe and effective as the predicate. The OTS 25-L has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the OTS

25-L and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the OTS 25-L is as safe and effective as the predicate. Thus, the OTS 25-L is substantially equivalent.