December 7, 2023

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

Re: K233429
Trade/Device Name: OTS 25
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 11, 2023
Received: October 11, 2023

Dear Ms. 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.

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,

Jesse Muir -S Digitally signed by Jesse Muir -S
Date: 2023.12.07 12:24:30 -05'00'

Jesse Muir, 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

INDICATIONS FOR USE

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)*

K233249

Device Name

OTS 25

Indications for Use *(Describe)*

The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.
The OTS 25 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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510(k) Summary

Prepared on: 2023-10-10

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OTS25
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number	888.3040
Product Code	MBI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K133224	Y-Knot All-Suture Anchor	MBI
K110145	JuggerKnot Soft Anchors	MBI

Device Description Summary

21 CFR 807.92(a)(4)

OTS 25 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

21 CFR 807.92(a)(5)

The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.
The OTS 25 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

21 CFR 807.92(a)(5)

The OTS 25 has the exact same intended use of its predicate device the ConMed's Y-Knot® RC All-Suture Anchor with two or three #2 Hi-Fi® Sutures (K133224). Namely, both devices are intended to reattach soft tissue to bone in orthopedic surgical procedures. The indications for use of the two devices are identical aside from differences in device name.
Both 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, both suture anchor systems stabilize the damaged soft tissue. In other words, the OTS 25 has the same exact intended use and indication for use as its predicate device. Thus, the OTS 25 satisfies the first criterion for a finding of substantial equivalence.

Technological Comparison

21 CFR 807.92(a)(6)

The OTS 25 and predicate device have bone anchoring and soft tissue attachment elements. Both 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 predicate 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 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.
Both suture anchors are inserted through a predrilled hole and therefore have the same insertion mechanism as its predicate 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 predicate's instruments as well, resulting in an equivalent, 8-step insertion method as its predicate.
The main difference between the OTS 25 and its predicate is the material of the anchor. While the Y-knot is made of flat braid of Ultra High Molecular Weight Polyethylene (UHMWPE), the OTS 25 anchor is made of a flat sleeve Braided polyester (PET). PET has been in use in other all-suture anchors, such as the JuggerKnot (K110145, reference device), and is a biocompatible, well-established material.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following performance testing has been completed for the POTS 25 Device:
- Pullout Testing (Static and Dynamic)
- SterilizationValidation, Pyrogenicity Testing, and Endotoxin Monitoring
- Packaging Testing, Shelf-life Testing
- Biocompatibility Testing

The series of tests, listed above, has been conducted and successfully completed. The results demonstrate that the OTS 25 provides adequate mechanical properties for its use.
Following nonclinical tests, it was concluded that OTS 25 is as safe, as effective, and performs at least as well as the legally marketed predicate device.