July 22, 2025

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

Re: K251310
Trade/Device Name: OTS 25-L (100-5)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 2, 2025
Received: July 2, 2025

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.

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 Ferreira, M.S.
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251310

Please provide the device trade name(s).

OTS 25-L (100-5)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251310

510(k) Summary

Prepared on: 2025-07-02

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OTS 25 -L (10 05)
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number	888 .3040
Product Code(s)	MBI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241234	OTS 25-L	MBI
K151068	Cayenne Medical's Surelock W Suture Anchor	MB I

Device Description Summary

21 CFR 807.92(a)(4)

OTS 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 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-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 21 CFR 807.92(a)(5)

The subject OTS 25-L has the same intended use and indications, technological characteristics, and principles of operation as the previously cleared predicates OTS Medical's OTS 25-L. The only change to the device is a labeling change to allow use of the device when packed with autologous bone marrow.

Technological Comparison 21 CFR 807.92(a)(6)

The subject OTS 25-L and predicate cleared OTS 25-L device (K241234) are identical in all technological characteristics. The only difference between the subject OTS 25-L and the cleared OTS 25-L (K241234) predicate is a change to the labeling which allows the extension component of the anchor above the bone surface to be optionally filled with autologous bone marrow to allow the porous, braided polyester to act an interface for augmentation of the soft tissue.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

GLP animal testing was performed on 8 animals at 6 weeks (3 control, 5 investigational) and 12 animals at 16 weeks (4 control, 8 investigational). The control device consisted of the cleared OTS 25 anchor (K233429) and the investigational device was the subject OTS 25-L anchor packed with autologous bone marrow/bone fragments. Animals underwent a Bankart surgical procedure involving unilateral exposure of the glenohumeral joint, a bone lesion creation, and OTS test articles implantation. In vivo assessments performed included blood collection, body weight, lameness, CT imaging (16 weeks only). Ex-vivo assessments included macroscopic analysis, microCT analysis, histopathology (organs and shoulder samples), and biomechanical testing (6 weeks only).

No clinical testing was performed to establish equivalence.

The results of the test demonstrated the investigational device was at least equivalent to the cleared predicate in terms of tissue healing and strength of attachment.