October 17, 2022

CTL Medical Corporation
% Barry Sands
President
Rqmis, Inc.
110 Haverhill Road, Suite 524
Amesbury, Massachusetts 01913

Re: K211785
Trade/Device Name: CASSATT™ SIJ Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: September 14, 2022
Received: September 15, 2022

Dear Barry Sands:

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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K211785

Device Name
CASSATT™ SIJ Fixation System

Indications for Use *(Describe)*

The CASSATT™ SIJ Fixation System is intended for fixation of sacroiliac joint disruptions and intended for sacroiliac joint fusion for conditions including.

- Sacroiliac joint disruptions,
- Degenerative sacroiliitis,
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

CTL Medical's CASSATT™ SIJ Fixation System

I. Submitter

Sean Suh
CTL Medical Corporation
4550 Excel Parkway, Suite 300
Addison, TX 75001
Phone: (214) 545-5820
Email: ssuh@ctlamedica.com

Contact Person:
Barry E. Sands
RQMIS Inc.
110 Haverhill Road, Suite 524
Amesbury, MA 01913
Phone: (978) 358-7307
Email: barrysands@rqmis.com
Facsimile: (978) 477-0206

II. Subject Device

Trade/proprietary name of device:	CASSATT™ SIJ Fixation System
Common or Usual Name:	CASSATT™ SIJ Fixation System
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 C.F.R. §888.3040
Classification:	Class II
Product code(s):	OUR

510(k) summary prepared: October 12, 2022

III. Predicate Devices

Triton Sacroiliac Joint Fixation System (Primary Predicate) (K211449)
Siconus SI Joint Fixation System (Additional predicate) (K162121)
Synthes Cannulated Screws (Additional predicate) (K021932)

IV. Device Description

The CASSATT™ SIJ Fixation System is a cannulated screw system, including head washer. The system offers various sizes to accommodate a wide range of anatomies. These devices come in various sizes to accommodate patient anatomy, which are all manufactured from titanium alloy, as specified in ASTM F136.

Indications for Use:

The CASSATT™ SIJ Fixation System is intended for fixation of sacroiliac joint disruptions and intended for sacroiliac joint fusion for conditions including:

- Sacroiliac joint disruptions,
- Degenerative sacroiliitis,
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

V. Comparison of Technological Characteristics with the Predicate Device:(Substantial Equivalence)

The subject device 'CASSATT™ SIJ Fixation System' and the primary predicate 'Triton Sacroiliac Joint Fixation System' (K211449) and additional predicates 'Siconus SI Joint Fixation System (K162121), 'Synthes Cannulated Screws' (K021932) have the same intended use/indication for use, materials, technological characteristics, and principles of operation. Thus, the CASSATT™ SIJ Fixation System is substantially equivalent to the primary and additional predicates .

VI. Performance Data

CTL Medical performed bench testing according to ASTM F2193, specifically Static and Dynamic cantilever bending, and screw insertion, pull-out, and static torsion tests were conducted as per ASTM F543. Additionally, the subject device CASSATT™ SIJ Fixation System (Full assembly: screw and washer) underwent testing according to modified ASTM 2193 to evaluate the strength characterization of the full assembly of CASSATT™ SIJ Fixation system.

The bench tests were conducted to demonstrate that the device meets its specifications and its intended use, as well as to verify the safety and performance of the device's functional features and operational parameters. In all instances the device functioned as intended, met the predefined acceptance criteria and all the results were satisfactory.

The mechanical tests performed indicate that the CASSATT™ SIJ Fixation system performs equally or better as compared to predicate devices.

VII. Conclusion

The CASSATT™ SIJ Fixation System has the same intended uses and same indications, technological characteristics, and principles of operation as of its primary and additional predicate devices. The technological differences between the subject device and the predicate do not raise new questions of safety and effectiveness. The performed mechanical tests demonstrate that any differences do not adversely affect the safety, effectiveness, or intended performance of the device. Thus, the subject device is substantially equivalent to the predicate device.