April 8, 2026

Tenon Medical
% Ethan Naylor
Vice President, Regulatory Affairs - Spine
MCRA, LLC
803 7th St. NW
Washington, District of Columbia 20001

Re: K260477
Trade/Device Name: CATAMARAN™ SI Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: February 17, 2026
Received: February 17, 2026

Dear Ethan Naylor:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MAZIAR SHAH-MOHAMMADI -S

[For] Brent Showalter, Ph.D.
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

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.	K260477

Please provide the device trade name(s).

CATAMARAN™ SI Joint Fusion System

Please provide your Indications for Use below.

The Tenon Medical Catamaran SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including:

• Sacroiliac joint disruptions and 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.

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

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

510(k) Summary

Device Trade Name:

Manufacturer: Tenon Medical
104 Cooper Ct
Los Gatos, CA 95032

Contact: Ethan Naylor
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MCRA, LLC
803 7th Street NW
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Prepared by: MCRA, LLC
803 7th Street NW
Washington, DC 20001
Office: 202.552.5800

Date Prepared: April 1, 2026

Trade Name: CATAMARAN™ SI Joint Fusion System

Common Name: Sacroiliac Joint Fixation

Classification: 21 CFR 888.3040

Product Code: OUR

Primary Predicate: CATAMARAN SI Joint Fusion System (K250403)

Additional Predicates: CATAMARAN SI Joint Fusion System (K180818)
CATAMARAN SI Joint Fusion System (K231944)

Device Description:
The CATAMARAN SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. The CATAMARAN SI Joint Fusion System was developed as a less invasive alternative to traditional open posterior surgical SI Joint fusion. The system consists of the CATAMARAN SI Joint Fixation Implant (Ti6A1-4V ELI Titanium alloy / ASTM F136) included in a reusable System Tray containing: Access, Drill and Delivery, Bone Graft

Packing, and Extraction Instruments. The CATAMARAN SI Joint Fixation Implants are designed in various widths and lengths, and allow autologous bone graft material placement in the barrels of the implant to support SI Joint fixation and fusion. The Instrument Set includes Class II single use and reusable surgical instruments designed to facilitate placement of the implant within the sacroiliac joint using an inferior-posterior surgical approach. The implants and associated instruments are provided clean and non-sterile and are designed for steam sterilization prior to use.

Indications for Use:
The Tenon Medical Catamaran SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including:

- Sacroiliac joint disruptions and 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.

Performance Testing:
The following performance testing has been conducted to support the subject Tenon Medical Catamaran SI Joint Fusion System 510(k):

- Biocompatibility Assessment per ISO 10993
- Sterilization Validation per ISO 17664
- Cadaver Study
- Usability Assessments
- Design Verification Evaluations

Substantial Equivalence:
The CATAMARAN SI Joint Fusion System and Instruments have the same technological characteristics and principles of operation as compared to the predicate device; the CATAMARAN Sacroiliac Joint Fixation System cleared in K250403, K231944, and K180818. The modifications to the Instruments do not raise any new types of safety or effectiveness questions between the CATAMARAN SI Joint Fusion System and the predicate devices.

Conclusion:
The subject CATAMARAN™ SI Joint Fusion System is substantially equivalent to the cited predicate devices.