Tenon Medical, Inc.
% Susan Noriega
Regulatory Affairs, Clinical and Quality Consultant
Lince Consulting, LLC
111 Deerwood Road, Suite 200
San Ramon, California 94583

August 24, 2023

Re: K231944
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: June 30, 2023
Received: June 30, 2023

Dear Susan Noriega:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.08.24 13:14:07 -04'00'

for

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)*
K231944

Device Name
CATAMARAN™ SI Joint Fusion System

Indications for Use *(Describe)*
The Tenon Medical CATAMARAN SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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
CATAMARAN™ SI Joint Fusion System

I. DATE PREPARED

June 30, 2023

II. 510(k) SUBMITTER

Tenon Medical, Inc.
104 Cooper Court
Los Gatos, CA 95032
Phone: (408) 649-5760

Contact Person:
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FDA Establishment Registration No.: 3015425107

III. DEVICE

Trade Name of Device:	CATAMARAN™ SI Joint Fusion System
Common or Usual Name:	Sacroiliac Joint Fixation
Classification:	Class II
Regulation Number:	21 CFR 888.3040; Smooth or threaded metallic bone fastener
Product Code:	OUR

IV. PREDICATE DEVICE

Primary Predicate Device	Manufacturer	Product Code	510(k)#	Clearance Date
CATAMARAN™ Sacroiliac Joint Fixation System	Tenon Medical	OUR	K180818	June 13, 2018

V. 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.

VI. 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.

VII. SUMMARY OF VERIFICATION AND VALIDATION ACTIVITIES

The subject 510(k) Submission requests MR Conditional Labeling for the CATAMARAN SI Joint Fusion Implant to support use in an MR Environment. MR Compatibility Assessments were performed using FDA Guidance: *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (May 20, 2021) and *Assessment of Radiofrequency Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices* (March 22, 2016). The results of the MR Compatibility testing support the use of the CATAMARAN SI Joint Fusion Implant in an MR Environment as MR Conditional.

Design Verification Standards Testing

MR Compatibility Assessment	• ASTM F2052-21 - *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* • ASTM F2119-13 (17) - *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants* • ASTM F2182-19e2 - *Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging* • ASTM F2213-17 - *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment* • ASTM F2503 -20 - *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

VIII. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The CATAMARAN SI Joint Fusion System has the same intended use, indications for use, technological characteristics (with minor changes to the instruments and system tray), and principles of operation as compared to the predicate device; the CATAMARAN Sacroiliac Joint Fixation System cleared in K180818.

Any minor differences between the CATAMARAN SI Joint Fusion System and the predicate device do not raise any new types of safety or effectiveness questions, including the MR Compatibility Assessment. Testing demonstrates that the CATAMARAN SI Joint Fusion System meets requirements for its intended clinical use.

IX. CONCLUSION

Based on the similarities in intended use, indications for use and technological characteristics, the subject CATAMARAN SI Joint Fusion System is substantially equivalent to the predicate device.