June 13, 2018

Tenon Medical, Inc.
% Ms. Jeannie Cecka
Regulatory Consultant
JGC, LLC
2100 Omega Road, Suite F
San Ramon, California 94583

Re: K180818
Trade/Device Name: Catamaran Sacroiliac Joint Fixation System (CAT 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: March 28, 2018
Received: March 29, 2018

Dear Ms. Cecka:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180818

Device Name
Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System)

Indications for Use *(Describe)*
The Tenon Medical Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation 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.

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.

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II. 510(k) Summary

ADMINISTRATIVE INFORMATION

Submitter:
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Official Correspondent:
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Regulatory Consultant
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Date Prepared: March 28, 2018

DEVICE NAME

Trade Name:	Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System)
Classification Name:	Sacroiliac Joint Fixation
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Product Code:	OUR
Regulation Number:	888.3040
Review Panel:	Orthopedic

Device Description:

The Tenon Medical Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System) was developed as a less invasive alternative to traditional open posterior surgical SIJ fusion. The Tenon Medical Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System) includes the Catamaran SIJ Implant and associated surgical instruments: an Access Set, a Drill/Delivery and an Accessory Set and an Extraction Set. The titanium implant consists of two hollow barrels connected by a bridge. During the procedure, autologous bone graft material is placed in the barrel of the implant to facilitate stabilization. The Catamaran SIJ Implant is available in two (2) different barrel diameters (7.5mm and 10mm) and two implant lengths (30mm and 40mm) for a total of four sizing options to fit patient anatomy. The Catamaran SIJ Implant is intended for single-use only. The implants and associated components are provided clean and non-sterile and designed for routine steam sterilization prior to use.

Indications for Use: The Tenon Medical Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System) is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Performance Data:
Performance testing, including biocompatibility, chemical characterization, mechanical static and dynamic shear testing, pull-out, cadaver and instrumentation testing was submitted to support the overall functionality and usability of the Tenon Medical Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System).

Predicate Devices:
- Medtronic Sofamor Danek Rialto™ SI Fusion System (K161210) - **Primary Predicate**
- Medtronic Inc. - SI-FIX Sacroiliac Joint Fusion System (MSB Sacroiliac Joint Fusion Device) (K110472)
- Si-Bone - iFuse Implant System (K131405)
- Synthes - 6.5mm Cannulated Screw (K021932)

Equivalence to Marketed Products:
Tenon Medical Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Tenon Medical Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System) is substantially equivalent to predicate devices based on a comparison including the following attributes:
- FDA Product Code
- Intended Use
- Technological Characteristics

Conclusions:
In summary, the Tenon Medical Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System) is substantially equivalent to predicate devices and is capable of performing in accordance with its intended use. The device does **not** raise any new or different questions or concerns of safety or effectiveness as compared to commercially available predicate devices.