September 2, 2022

Camber Spine Technologies, LLC
Christine Scifert
Official Correspondent
501 Allendale Road
King of Prussia, Pennsylvania 19604

Re: K203503
Trade/Device Name: Camber Sacroiliac (SI) 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: August 24, 2022
Received: August 26, 2022

Dear Christine Scifert:

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,

Anne D. Talley -S 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)*
K203503

Device Name
Camber Sacroiliac (SI) Fixation System

Indications for Use *(Describe)*
The Camber Sacroiliac (SI) Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. When the Camber SI Fixation System is implanted, it must be used with a SICONUS SI Joint Fixation System screw implanted across the same 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.

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510(k) Summary

Device Trade Name:	Camber Sacroiliac (SI) Fixation System
Manufacturer:	Camber Spine Technologies 501 Allendale Road King of Prussia, PA 19406
Company Contact:	Noel Hetrick Nhetrick@cambermedtech.com
Official Correspondent:	Christine Scifert Partner, MRC Global Christine.scifert@askmrcglobal.com 901-831-8053
Date Prepared:	September 2, 2022
Classifications:	21 CFR §888.3040, Smooth or Threaded Metallic Bone Fixation Fastener
Class:	II
Product Code:	OUR
Primary Predicate:	Tenon Medical Catamaran Sacroiliac Joint Fixation System (K180818)
Reference Predicate(s):	Camber Spine ENZA-A Titanium ALIF device (K173432)

Indications For Use:

The Camber Sacroiliac (SI) Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. When the Camber SI Fixation System is implanted, it must be used with a SICONUS SI Joint Fixation System screw implanted across the same sacroiliac joint.

Device Description:

The Camber SI Fixation System is a fusion device consisting primarily of an open architecture 3D generated titanium body to permit bone growth (fusion) throughout the implant. All internal surfaces have a roughened texture. The upper and lower faces have specifically designed surface approximately 0.5 mm thick to provide a trabecular support structure. In addition, the device utilizes a set of two sharpened anchor plates that translate from within the device in slightly angular opposing lateral directions which provide an anchoring system to fixate the implant between ilium and sacrum. The Camber SI Fixation System device has one footprint: 23x26 mm. Implant heights

range from 9 to 13mm in 2 mm increments with 8° angulation.

Predicate Device:

The subject device, the Camber Sacroiliac (SI) Fixation System, is substantially equivalent to the Tenon Catamaran SI Joint Fixation System (K180818) in terms of Indications for use. The reference predicate, ENZA-A Titanium ALIF device (K173432) has an identical anchoring system as the Camber SI Fixation System.

Performance Testing Summary:

Testing performed indicate that the Camber SI Fixation System is as mechanically sound as the cleared devices. Testing included static vertical shear, static vertical shear stiffness, dynamic vertical shear endurance, implant dislodgement and anchor collapse force. The results demonstrate that the acceptance criteria defined by predicate device performance were met. Cadaveric and usability testing was done to establish substantial equivalence.

Substantial Equivalence:

The subject Camber Sacroiliac (SI) Fixation System was demonstrated to be substantially equivalent to primary predicate, Tenon Catamaran Sacroiliac Joint Fixation System (K180818) and the reference predicate, the ENZA-A Titanium ALIF device (K173234) with regards to indications for use, design inputs, materials, performance and/or manufacturing.

Conclusion:

Camber Spine Technologies has provided sufficient information to demonstrate the Camber Sacroiliac (SI) Fixation System is substantially equivalent to primary predicate, Tenon Catamaran Sacroiliac Joint Fixation System (K180818) and the reference predicate, the ENZA-A Titanium ALIF device (K173234) with regards to indications for use, design inputs, materials, performance and/or manufacturing. .