



February 27, 2024

Camber Spine Technologies
% Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
Mcra, LLC
803 7th Street NW, Third Floor
Washington, District of Columbia 20001

Re: K233972

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: December 15, 2023
Received: December 15, 2023

Dear Justin Eggleton:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Colin
O'Neill -S 

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

Indications for Use

510(k) Number (if known)
K233972

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.

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
510 Allendale Road
King of Prussia, PA 19406
Phone: 484-420-4286

Contact: Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
MCRA, LLC

Prepared by: MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: December 15, 2023

Classifications: 21 CFR §888.3040

Class: II

Product Codes: OUR

Primary Predicate: Rialto SI Fusion System, Medtronic Sofamor Danek, K161210

Additional Predicate: Camber SI Fixation System, Camber Spine Technologies, LLC, K203503

Indications For Use:

The Camber Sacroiliac (SI) Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Device Description:

The Camber SI Fixation System is comprised of a single-use implant and reusable instruments. The Camber SI Fixation System implant is intended to be implanted in the undeployed state via a posterior approach into the sacroiliac joint. Once implanted, the anchors are deployed to stabilize the sacroiliac joint. The Camber SI Fixation System implant includes multiple openings to allow surgeons to fill them with autogenous bone graft.

Performance Testing Summary:

A battery of performance testing has been performed on the subject device to demonstrate its substantial equivalence to the predicate device, including:

- Static vertical shear and dynamic vertical shear
- Expulsion
- Pin retaining
- Anchor strength
- Cadaver testing

Substantial Equivalence:

It has been determined that the Camber SI Fixation System is substantially equivalent to the following predicate and reference device for the purpose of introducing to interstate commerce.

- Primary Predicate: Rialto SI Fusion System, Medtronic Sofamor Danek, K161210
- Additional Predicate: Camber SI Fixation System, Camber Spine Technologies, LLC, K203503

Conclusion:

The Camber SI Fixation System is substantially equivalent to the primary and additional predicates with respect to intended use, materials, design, and function.