Camber Spine Technologies, LLC
% Christine Scifert
Partner
MRC Global, LLC
9085 E Mineral Circle, Suite 110
Centennial, Colorado 80112

April 16, 2024

Re: K232256
Trade/Device Name: Alcantara Thoracolumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 21, 2024
Received: March 21, 2024

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 (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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.04.16 09:04:41 -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.

Submission Number *(if known)*

K232256

Device Name

Alcantara Thoracolumbar Plate System

Indications for Use *(Describe)*

The Camber Spine Alcantara Thoracolumbar Plate System 2, 3 and 4-screw plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); Pseudoarthrosis; Spondylolysis; Spondylolisthesis; Spinal stenosis; Tumors; Trauma (i.e. Fractures including dislocation and subluxation) Deformities (i.e. Scoliosis, Kyphosis or Lordosis); Failed Previous Fusion.

The Camber Spine Alcantara Thoracolumbar Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Alcantara Thoracolumbar Plate System
19 March 2024

Company: Camber Spine Technologies
501 Allendale Rd
King of Prussia, PA 19406
(484) 427-7060

Company Contact: Brooks McAdam
Chief Operating Officer
(484) 427-7060
bmcadam@cambermedtech.com

Official Correspondent: Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: Alcantara Thoracolumbar Plate System

Common Name: Appliance, Fixation, Intervertebral Body

Classification: Class II

Regulation Number: 21 CFR 888.3060 (Spinal Intervertebral Body Fixation Orthosis)

Panel: Orthopedic

Product Code: KWQ

Device Description:
The Camber Spine Alcantara Thoracolumbar Plate System is an anterior/ anterolateral/ lateral plate system that may be used in the thoracic, lumbar, and sacral spine (T1-S1). The Camber Spine Alcantara Thoracolumbar Plate System consists of plates that include bone screw holes and blocking mechanisms to prevent screw back-out, and bone screws, as well as associated manual general surgical instrumentation. The implants are available in a variety of sizes to accommodate various patient anatomies. All Alcantara Thoracolumbar plates and screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

Indications for Use:
The Camber Spine Alcantara Thoracolumbar Plate System 2, 3 and 4-screw plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic

studies); Pseudoarthrosis; Spondylolysis; Spondylolisthesis; Spinal stenosis; Tumors; Trauma (i.e. Fractures including dislocation and subluxation) Deformities (i.e. Scoliosis, Kyphosis or Lordosis); Failed Previous Fusion.

The Camber Spine Alcantara Thoracolumbar Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

Substantial Equivalence:

The subject Alcantara Thoracolumbar Plate System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Meditech Spine Cure™ Lumbar Plate – K171538

Additional Predicates:

- Choice Spine Raven Lumbar Plate System – K183214
- Precision Spine Accufit – K162211, K220324
- Stryer LITe® Plate System – K142699, K150449
- Corelink, Oro Lateral Plate System – K231743
- Camber Spine Technologies FORTICO Anterior Cervical Fixation System – K191584
- Camber Spine Technologies SPIRA-T Oblique Posterior Lumbar Spacers – K210595

The subject Alcantara Thoracolumbar Plate System is similar to the predicate devices. The indications for use and geometry of the predicate devices are inclusive of those of the subject device. The materials of the subject device are identical to that of the predicate devices. The manufacturing processes and materials are identical to those of the previously cleared reference devices FORTICO Anterior Cervical Fixation System (K191584). Performance testing has concluded that the subject Alcantara Thoracolumbar Plate System meets or exceeds the acceptance criteria defined in FDA Guidance document Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff or that of the predicates LITe Plate System (K142699) and Oro Lateral Plate System (K231743). Therefore, it is concluded that the subject device demonstrates substantial equivalence to the predicate devices and no new issues of safety and effectiveness have been created.

Performance Testing:

Mechanical testing, including Static and Dynamic Compression Bending, and Static Torsion per ASTM F1717-21, has been performed on the subject Alcantara Thoracolumbar Plate System and has shown the subject devices to be substantially equivalent to the predicate interbody devices.

Conclusion:

Based on the performance analysis and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.