March 30, 2023

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

Re: K221324
Trade/Device Name: ENZA®-O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: January 24, 2023
Received: January 24, 2023

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,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
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)*
K221324

Device Name
ENZA®-O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF)

Indications for Use *(Describe)*
The Camber Spine ENZA®- O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Camber Spine ENZA®- O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF) is intended to be used with additional FDA-cleared supplementary fixation systems. The Camber Spine ENZA®- O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF) must be used with autogenous graft material or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

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.

510(k) Summary
ENZA®-O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF)
January 20, 2023

Company: Camber Spine Technologies
501 Allendale Road
King of Prussia, PA 19406

Company Contact: Brooks McAdam
VP of Operations
bmcadam@cambermedtech.com
757-876-4250

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

Trade Name: ENZA®-O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF)

Common Name: Intervertebral Fusion Device with Integrated Fixation, Lumbar

Classification: Class II

Regulation Number: 21 CFR 888.3080

Panel: Orthopedic

Product Code: OVD

Device Description:
The Camber Spine Technologies ENZA®-O Titanium ALIF is a lumbar interbody fusion device that has a hollow chamber to permit packing with autogenous graft material or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. The superior and inferior surfaces of the device have a rough surface to help prevent movement of the device while fusion takes place. Additionally, the device has integrated fixation through superior and inferior anchoring plates. These implants may be implanted via an anterior oblique lateral approach. Patients with previous non-fusion spinal surgery at the treated level may be treated.

Camber Spine ENZA®-O device body is additively manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F3001-14. The internal device components (anchor plates, deployment ram, assembly pin and retention blocking screw) are manufactured from titanium alloy (Ti-6Al-4V) per ASTM F136. The internal sheer pin component is manufactured from PEEK per ASTM F2026.

Indications for Use:

The Camber Spine ENZA®- O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Camber Spine ENZA®- O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF) is intended to be used with additional FDA-cleared supplementary fixation systems. The Camber Spine ENZA®- O Titanium Lateral Anterior Lumbar Interbody Fusion (ALIF) must be used with autogenous graft material or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

Substantial Equivalence:
The subject ENZA®-O is substantially equivalent to the following predicate devices:

Primary Predicate:

- Camber Spine Technologies – ENZA®-A (K173432)

Additional Predicate :

- Camber Spine Technologies – SPIRA®-T Oblique Posterior Lumbar Spacers, SPIRA®-P Posterior Lumbar Spacers (K210595)

There are differences between the subject ENZA®-O and the primary predicate ENZA®-A interbody fusion device. The differences include the design of the blocking screw, deployment ram, and some internal features. The Overall Geometry and Materials of the subject device are identical to those of the predicate device. The indications for use of the subject device are identical to those of the primary predicate ENZA®-A device, with the addition of the use allograft, which is similar to the secondary predicate SPIRA® devices (K210595) Testing shows that the subject ENZA®-O performs equivalent to the ENZA®-A (K173432). Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:
Mechanical testing, including static and dynamic compression shear, static torsion, static and dynamic axial compression per ASTM F2077, as well as expulsion have been performed on the subject ENZA®-O interbody devices. The results have shown them to be substantially equivalent to the predicate interbody devices.

Conclusion:
Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.