April 18, 2018

Camber Spine Technologies
% Paul Speidel
Lead Regulatory Consultant
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K173432
Trade/Device Name: ENZA™-A Titanium ALIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 6, 2018
Received: March 16, 2018

Dear Mr. Speidel:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -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)*
K173432

Device Name

ENZA™-A Titanium ALIF

Indications for Use *(Describe)*

The Camber Spine Technologies ENZA™-A Titanium 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 Technologies ENZA™-A Titanium ALIF is intended to be used with additional FDA-cleared supplementary fixation systems. The Camber Spine Technologies ENZA™-A Titanium ALIF system must be used with autogenous graft material.

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

Camber Spine Technologies ENZA™-A Titanium ALIF

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Camber Spine Technologies
418 E. Lancaster Ave.
Wayne, PA 19087
Phone: 484.318.8031

Contact Person:
Mr. Damian Heinz
Engineering Support Manager
The Institute for Musculoskeletal Science and Education
418 E. Lancaster Ave.
Wayne, PA 19087
Phone: 484.420.4286
Fax: 484.318.8031
Email: dheinz@imseinstitute.org

Date Prepared: April 18, 2018

Name of Device and Name/Address of Sponsor

Trade Name: ENZA™-A Titanium ALIF
Camber Spine Technologies
418 E. Lancaster Ave.
Wayne, PA 19087

Common or Usual Name

Device Type: Intervertebral Fusion Device with Bone Graft, Lumbar

Classification Name

Intervertebral body fusion device (21 CFR 888.3080) (Product Code: OVD)

Predicate Devices

The subject ENZA™-A Titanium ALIF device was demonstrated to be substantially equivalent to predicates Camber Spine ENZA Zero-Profile Anterior Interbody Fusion Device (K153720) and Camber Spine SPIRA Open Matrix ALIF Device (K162986) with respect to indications, design, materials, function, manufacturing, and/or performance.

The primary predicate device is ENZA Zero-Profile Anterior Interbody Fusion Device (K153720).

Device Description

The Camber Spine Technologies ENZA™-A Titanium ALIF is an Interbody Fusion Device that has a hollow chamber to permit packing with autogenous graft material 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 a laparoscopic or an open anterior approach. Patients with previous non-fusion spinal surgery at the treated level may be treated.

Intended Use / Indications for Use

The Camber Spine Technologies ENZA™-A Titanium 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 Technologies ENZA™-A Titanium ALIF is intended to be used with additional FDA-cleared supplementary fixation systems. The Camber Spine Technologies ENZA™-A Titanium ALIF system must be used with autogenous graft material.

Technological Characteristics

The Camber Spine Technologies ENZA™-A Titanium ALIF is an Interbody Fusion Device that has spiral support arches to allow for a hollow chamber to permit packing with autogenous bone 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.

Performance Data

Testing performed indicate that the ENZA™-A Titanium ALIF is as mechanically sound as predicate devices. Testing included static compression, static compression-shear, dynamic compression, dynamic compression-shear, expulsion, and subsidence per ASTM F2077-14 and F2267-04. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Substantial Equivalence

The ENZA™-A Titanium ALIF is as safe and effective as the Camber Spine ENZA Zero-Profile Anterior Interbody Fusion Device (K153720) and Camber Spine SPIRA Open Matrix ALIF Device (K162986). The ENZA™-A Titanium ALIF has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the ENZA™-A Titanium ALIF and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that ENZA™-A Titanium ALIF is as safe and effective as Camber Spine ENZA Zero-Profile Anterior Interbody Fusion Device (K153720) and Camber Spine SPIRA Open Matrix ALIF Device (K162986). The ENZA™-A Titanium ALIF is substantially equivalent.