DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 3, 2016

Camber Spine Technologies
% Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisors, LLC
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K153720
Trade/Device Name: ENZA Zero-Profile Anterior Interbody Fusion
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: April 1, 2016
Received: April 4, 2016

Dear Mr. 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 (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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153720

Device Name
ENZA Zero-Profile Anterior Interbody Fusion

Indications for Use *(Describe)*

The Camber Spine Technologies ENZA Zero-Profile Anterior Interbody Fusion is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The Camber Spine Technologies ENZA Zero-Profile Anterior Interbody Fusion is intended to be used with additional FDA-cleared supplementary fixation systems.

The Camber Spine Technologies ENZA Zero-Profile Anterior Interbody Fusion system must be used with bone grafting material (autograft only).

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: ENZA Zero-Profile Anterior Interbody Fusion

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

Contact:
Mr. Michael Black
Director of Engineering
Phone: (855) 899.9869

Prepared by:
Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
jeggleton@mcra.com

Date Prepared: April 1, 2016

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: OVD

Primary Predicate: LDR ROI-A (K110327)

Additional Predicate: Theken Spine Vu aPOD (K101310)

Reference Devices: Renovis S128 PEEK ALIF (K131122), Centinel Spine STALIF TT (K073109), Alphatec Spine Solus Zero Profile Cage (K123993)

Indications For Use:
The Camber Spine Technologies ENZA Zero-Profile Anterior Interbody Fusion is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The Camber Spine Technologies ENZA Zero-Profile Anterior Interbody Fusion is intended to be used with additional FDA-cleared supplementary fixation systems.

The Camber Spine Technologies ENZA Zero-Profile Anterior Interbody Fusion system must be used with bone grafting material (autograft only).

Device Description:
The Camber Spine Technologies ENZA Zero-Profile Anterior Interbody Fusion is an Interbody Fusion Device that has a hollow chamber to permit packing with bone graft to facilitate fusion. The superior and inferior surfaces of the device have a pattern of teeth to provide increased stability and to help prevent movement of the device. The device has a built-in fixation mechanism that is manually deployed into the vertebral bodies by the operating surgeon.

Predicate Device:
The subject ENZA Zero-Profile Anterior Interbody Fusion device is substantially equivalent to predicates Theken Spine Vu aPOD (K101310) and LDR ROI-A (K110327) with respect to indications, design, function, and performance.

Non-Clinical Performance Testing and Substantial Equivalence:
Testing performed indicate that the ENZA Zero-Profile Anterior Interbody Fusion is as mechanically sound as predicate devices. Testing included static compression, static torsion, static compression-shear, dynamic compression, dynamic torsion, dynamic compression-shear, expulsion, and subsidence per ASTM F2077-14 and F2267-04. Wear testing was also performed to evaluate wear particulate. Additionally, blade deployment testing was conducted to evaluate blade performance. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Conclusion:
Camber Spine Technologies provided sufficient information to demonstrate the ENZA Zero-Profile Anterior Interbody Fusion is substantially equivalent to predicates Theken Spine Vu aPOD (K101310) and LDR ROI-A (K110327) with respect to indications, design, function, and performance.