February 2, 2018

Camber Spine Technologies
% Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K173800
Trade/Device Name: Camber Spine Technologies SPIRA – V™ Open Matrix Corpectomy Cage
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: December 13, 2017
Received: December 14, 2017

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.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173800

Device Name
Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy Cage

Indications for Use *(Describe)*
The Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy Cage is indicated for use in the Thoracolumbar Spine (T1-L5) to replace collapsed, damaged, or an unstable vertebral body due to tumor or trauma (i.e., fracture). The Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy is intended to be used with additional FDA-cleared supplementary fixation systems.

The Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy Cage 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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510(k) Summary

Device Trade Name:	Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy Cage
Manufacturer:	Camber Spine Technologies 418 E. Lancaster Ave. Wayne, PA 19087
Contact:	Mr. Daniel Pontecorvo CEO Phone: (484)-427-7060
Prepared by:	Justin Eggleton Musculoskeletal Clinical Regulatory Advisers, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Phone: (202) 552-5800 jeggleton@mcra.com
Date Prepared:	January 23, 2018
Classifications:	21 CFR §888.3060, Spinal intervertebral body fixation orthosis
Class:	II
Product Codes:	MQP
Primary Predicate:	Camber Spine VERTA (K143490)
Additional Predicates:	Osteotech VBR (K012254), Interpore Geo Structure (K010530)
Reference Devices:	Camber Spine SPIRA-C Open Matrix Cervical Interbody (K172446), Rezaian Fixator (K841189)

Indications for Use:
The Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy Cage is indicated for use in the Thoracolumbar Spine (T1-L5) to replace collapsed, damaged, or an unstable vertebral body due to tumor or trauma (i.e., fracture). The Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy is intended to be used with additional FDA-cleared supplementary fixation systems.

The Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy Cage system must be used with autogenous graft material.

Device Description:
The Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy Cage is a device that has spiral supports 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.

Predicate Device:
The subject Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy Cage is equivalent to the primary predicate device, Camber Spine VERTA (K143490). Additional predicates were presented, including the Osteotech VBR (K012254) and Interpore Geo Structure (K010530). Comparisons were made to reference devices, including the Camber Spine SPIRA-C Open Matrix Cervical Interbody (K172446) and Rezaian Fixator (K841189).

Performance Testing Summary:
Testing performed indicate that the Camber Spine Technologies SPIRA-V Open Matrix Corpectomy Cage is as mechanically sound as predicate devices. Testing included static compression, static torsion, dynamic compression, dynamic torsion, subsidence, and expulsion per ASTM F2077-14 and F2267-04. A particulate analysis was performed in accordance with ASTM F1877-16. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Substantial Equivalence:
The subject Camber Spine Technologies SPIRA-V™ Open Matrix Corpectomy Cage is equivalent to the primary predicate device, Camber Spine VERTA (K143490) with respect to indications, design, materials, function, manufacturing, and/or performance. Additional predicates were presented, including the Osteotech VBR (K012254) and Interpore Geo Structure (K010530). Comparisons were made to reference devices, including the Camber Spine SPIRA-C Open Matrix Cervical Interbody (K172446) and Rezaian Fixator (K841189).

Conclusion:
Camber Spine Technologies provided sufficient information to demonstrate the Camber Spine Technologies SPIRA-V Open Matrix Corpectomy Cage is equivalent to primary predicate, Camber Spine VERTA (K143490) with respect to indications, design, materials, function, manufacturing, and/or performance. Additional predicates, Osteotech VBR (K012254) and Interpore Geo Structure (K010530), were presented for additional comparisons. Additional comparisons were made to other reference devices, including the Camber Spine SPIRA-C Open Matrix Cervical Interbody (K172446), Rezaian Fixator (K841189).