November 7, 2017

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

Re: K172446
Trade/Device Name: SPIRA-C Open Matrix Cervical Interbody
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: August 10, 2017
Received: August 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.

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 (DICE) 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 (DICE) 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,

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)*
K172446

Device Name
SPIRA-C Open Matrix Cervical Interbody

Indications for Use *(Describe)*

The Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody is indicated for use at one or two contiguous levels in the cervical spine, from C3-C7, in skeletally mature patients who have had six weeks of non-operative treatment for the degenerative disk disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody is intended to be used with additional FDA-cleared supplementary fixation systems.

The Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody system must be used with autogenous bone graft 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)

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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"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

Device Trade Name: SPIRA-C Open Matrix Cervical Interbody

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: October 12, 2017

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: ODP

Primary Predicate: Camber Spine Coveris (K133529)

Additional Predicate(s): 4WEB Medical CERVICAL CAGE Spinal Truss System (K142112, K121741)

Reference Device: Camber Spine Technologies SPIRA Open Matrix ALIF (K162986)

Indications For Use:
The Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody is indicated for use at one or two contiguous levels in the cervical spine, from C3-C7, in skeletally mature patients who have had six weeks of non-operative treatment for the degenerative disk disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody is intended to be used with additional FDA-cleared supplementary fixation systems.

The Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody system must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

Device Description:
The Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody is a Cage 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 SPIRA-C Open Matrix Cervical Interbody is substantially equivalent to primary predicate, Camber Spine Coveris (K133529), and additional predicate 4WEB Medical CERVICAL CAGE Spinal Truss System (K121741)

Performance Testing Summary:
Testing performed indicate that the SPIRA-C Open Matrix Cervical Interbody is as mechanically sound as predicate devices. Testing included static compression, static compression-shear, static torsion, dynamic compression, dynamic compression-shear, dynamic torsion, 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 subject SPIRA-C Open Matrix Cervical Interbody device was demonstrated to be substantially equivalent to primary predicate, Camber Spine Coveris (K133529), and additional predicate 4WEB Medical CERVICAL CAGE Spinal Truss System (K142112, K121741) with respect to indications, design, materials, function, manufacturing, and/or performance. Additionally, the subject 510(k) referenced Camber Spine Technologies SPIRA Open Matrix ALIF (K162986) to establish equivalent biocompatibility.

Conclusion:
Camber Spine Technologies provided sufficient information to demonstrate the SPIRA-C Open Matrix Cervical Interbody is substantially equivalent to primary predicate, Camber Spine Coveris (K133529), and additional predicate 4WEB Medical CERVICAL CAGE Spinal Truss System (K121741) with respect to indications, design, materials, function, manufacturing, and/or performance.