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

June 12, 2017

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

Re: K162986
Trade/Device Name: SPIRA™ Open Matrix ALIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 8, 2017
Received: May 10, 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 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,

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)*

K162986

Device Name
SPIRA™ Open Matrix ALIF

Indications for Use *(Describe)*

The Camber Spine Technologies SPIRA™ Open Matrix 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 SPIRA™ Open Matrix ALIF is intended to be used with additional FDA-cleared supplementary fixation systems.

The Camber Spine Technologies SPIRA™ Open Matrix 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)

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)*

510(k) Summary

Device Trade Name: SPIRA™ Open Matrix ALIF

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

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

Prepared by:
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Date Prepared: June 9, 2017

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: MAX

Primary Predicate: 4WEB Medical ALIF Spinal Truss System (K083894, K112316)

Additional Predicate(s): Alphatec Spine Novel (K080699, K090782), Zimmer Spine InFix Anterior Lumbar System (K132790, K143297), and Scient'x Tribeca Cage (K080588).

Indications For Use:
The Camber Spine Technologies SPIRA Open Matrix 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 SPIRA Open Matrix ALIF is intended to be used with additional FDA-cleared supplementary fixation systems. The Camber Spine Technologies SPIRA Open Matrix ALIF system must be used with autogenous graft material.

Device Description:
The Camber Spine Technologies SPIRA Open Matrix 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.

Predicate Device:
The subject SPIRA Open Matrix ALIF device is substantially equivalent to predicates 4WEB Medical ALIF Spinal Truss System (K083894, K112316), Alphatec Spine Novel (K080699, K090782), Zimmer Spine InFix Anterior Lumbar System (K132790, K143297), and Scient'x Tribeca Cage (K080588) with respect to indications, design, materials, function, manufacturing, and/or performance.

Performance Testing Summary:
Testing performed indicate that the SPIRA Open Matrix 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 subject SPIRA Open Matrix ALIF device was demonstrated to be substantially equivalent to predicates 4WEB Medical ALIF Spinal Truss System (K083894, K112316), Alphatec Spine Novel (K080699, K090782), Zimmer Spine InFix Anterior Lumbar System (K132790, K143297), and Scient'x Tribeca Cage (K080588) with respect to indications, design, materials, function, manufacturing, and/or performance.

Conclusion:
Camber Spine Technologies provided sufficient information to demonstrate the SPIRA Open Matrix ALIF is substantially equivalent to predicates 4WEB Medical ALIF Spinal Truss System (K083894, K112316), Alphatec Spine Novel (K080699, K090782), Zimmer Spine InFix Anterior Lumbar System (K132790, K143297), and Scient'x Tribeca Cage (K080588) with respect to indications, design, materials, function, manufacturing, and/or performance.