April 24, 2020

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

Re: K193153
Trade/Device Name: SPIRA-C Integrated Fixation System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: April 17, 2020
Received: April 17, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K193153

Device Name
SPIRA-C Integrated Fixation System

Indications for Use *(Describe)*
The Camber Spine Technologies SPIRA-C Integrated Fixation System consists of a stand-alone interbody device indicated for use at one or two contiguous levels in the cervical spine, from C2-C3 disc to the C7-T1 disc, in skeletally mature patients who have had six weeks of non-operative treatment for the cervical disk disease. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The SPIRA-C Integrated Fixation System must be used with internal screw fixation. The Camber Spine Technologies SPIRA-C Integrated Fixation System must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.

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: SPIRA-C Integrated Fixation System

Manufacturer:
Camber Spine Technologies
501 Allendale Road
King of Prussia, PA 19406

Contact:
Mr. Daniel Pontecorvo
CEO
Phone: (484)-427-7060

Prepared by:
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Date Prepared: April 23, 2020

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Code: OVE

Primary Predicate: Stryker Spine Anchor C (K102606)

Additional Predicate(s): Centinel Spine STALIF C (K120819, K072415), Spinal Elements Mosaic-C (K133218, K071833), and 4WEB Cervical Spinal Truss System-Stand Alone (K190870)

Reference Devices: Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody (K172446), Camber Spine Technologies Coveris Cervical Cage (K170050), Fortico Anterior Cervical Fixation System (K191584), ORTHROS™ Posterior Stabilization System; ORTHROS™ MIS Posterior Stabilization System (K180980)

Indications For Use:

The Camber Spine Technologies SPIRA-C Integrated Fixation System consists of a stand-alone interbody device indicated for use at one or two contiguous levels in the cervical spine, from C2-C3 disc to the C7-T1 disc, in skeletally mature patients who have had six weeks of non-operative treatment for the cervical disk disease. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The SPIRA-C Integrated

Fixation System must be used with internal screw fixation. The Camber Spine Technologies SPIRA-C Integrated Fixation System must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.

Device Description:
The SPIRA®-C Integrated Fixation System consists of a stand-alone interbody fusion device with internal screw fixation. The SPIRA®-C Integrated Fixation System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one or two levels from the C2-C3 disc to the C7-T1 disc. The system is comprised of a Titanium Alloy (Ti-6Al-4V ELI) interbody cage and screws. The SPIRA®-C Integrated Fixation System cages are provided in 7 degrees of lordosis, 6-12mm heights, 14-20mm widths and 13-16mm depths. This device must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. The SPIRA®-C Integrated Fixation System is that has spiral supports to allow for a hollow chamber to permit packing with autogenous and/ or allogenic 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. The titanium alloy interbody cage also comes preassembled with a titanium alloy, built-in rotary locking mechanism. The bone screws used with this device are provided in self-drilling and self-tapping options, along with variable angle and fixed angle trajectories, and are manufactured from medical grade titanium alloy. The bone screws are provided in 3.5mm and 4.0mm diameters and 12-18mm lengths.

Predicate Device:
The subject SPIRA-C Integrated Fixation System is substantially equivalent to primary predicate, Stryker Spine Anchor C (K102606), and additional predicates listed as Centinel Spine STALIF C (K120819, K072415), Spinal Elements Mosaic-C (K133218, K071833), and 4WEB Cervical Spinal Truss System-Stand Alone (K190870). A reference was made to the Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody (K172446), Camber Spine Technologies Coveris Cervical Cage (K170050), Fortico Anterior Cervical Fixation System (K191584) and Camber Spine ORTHROS™ Posterior Stabilization System; ORTHROS™ MIS Posterior Stabilization System (K180980) with regards to design, materials, and manufacturing.

Performance Testing Summary:
Testing performed indicate that the SPIRA-C Integrated Fixation System 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 F2077-18 and F2267-04. Additional mechanical testing was performed to evaluate the screw and anti-backout mechanism resistance to pushout forces. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Substantial Equivalence:
The subject SPIRA-C Integrated Fixation System device was demonstrated to be substantially equivalent to primary predicate, Stryker Spine Anchor C (K102606) along with additional predicates listed as Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody (K172446), Centinel Spine STALIF C (K120819, K072415), Spinal Elements Mosaic-C (K133218, K071833), 4WEB Cervical Spinal Truss System-Stand Alone (K190870) with respect to indications, design, materials, function, manufacturing, and/or performance. A reference was made to the Camber Spine Technologies Coveris Cervical Cage (K170050), Fortico Anterior Cervical Fixation System (K191584), and Camber Spine ORTHROS™ Posterior Stabilization System;

ORTHROS™ MIS Posterior Stabilization System (K180980) with regards to design inputs, materials, and manufacturing to further support the substantial equivalence profile.

Conclusion:

Camber Spine Technologies provided sufficient information to demonstrate the SPIRA-C Integrated Fixation System is substantially equivalent to primary predicate, Stryker Spine Anchor C (K102606) along with additional predicates listed as Centinel Spine STALIF C (K120819, K072415), and Spinal Elements Mosaic-C (K133218, K071833) with respect to indications, design, materials, function, manufacturing, and/or performance. Comparisons to the reference device Camber Spine Technologies SPIRA-C Open Matrix Cervical Interbody (K172446), Camber Spine Technologies Coveris Cervical Cage (K170050), Fortico Anterior Cervical Fixation System (K191584), and ORTHROS™ Posterior Stabilization System; ORTHROS™ MIS Posterior Stabilization System (K180980) provided additional benefit to the decision-making process.