March 22, 2023

Camber Spine Technologies
℅ Christine Scifert
Partner
MRC Global, LLC
9085 E. Mineral Cir., Suite 110
Centennial, Colorado 80112

Re: K223837
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: January 25, 2023
Received: January 26, 2023

Dear Christine Scifert:

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,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223837

Device Name
SPIRA®-C Integrated Fixation System

Indications for Use *(Describe)*
The SPIRA®-C Integrated Fixation System is intended for use as a cervical intervertebral fusion system indicated for use at one or two contiguous levels in the cervical spine (C2-T1), in skeletally mature patients who have had six weeks of non-operative treatment for the following: degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), cervical spondylotic myelopathy, trauma (such as fracture or dislocation), spinal stenosis, deformities or curvatures (such as scoliosis, kyphosis, or lordosis), pseudarthrosis, and failed previous fusion. The device is intended for use with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

When used with screws, SPIRA®-C Integrated Fixation System are standalone interbody fusion devices intended for use at one or two contiguous levels in the cervical spine (C2-T1). When used with anchors, SPIRA®-C Integrated Fixation System is intended for use at one level of the cervical spine with additional supplemental fixation such as posterior cervical screw fixation.

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.

510(k) Summary
Camber SPIRA®-C Integrated Fixation System
16 March 2023

Company: Camber Spine Technologies
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King of Prussia, PA 19406
(484) 427-7060

Company Contact: Brooks McAdam
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Official Correspondent: Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: SPIRA®-C Integrated Fixation System

Common Name: Intervertebral Fusion Device With Integrated Fixation, Cervical

Classification: Class II

Regulation Number: 21 CFR 888.3080 (Intervertebral body fusion device)

Panel: Orthopedic

Product Code: OVE

Device Description:
The SPIRA®-C Integrated Fixation System cages are interbody cages with integrated screws to provide additional fixation in interbody fusion procedures. The subject submission seeks to add anchors as an option for use for integrated fixation. The SPIRA-C® Integrated Fixation System cages are provided various heights and footprints to accommodate patient anatomy. The SPIRA®-C Integrated Fixation System has spiral supports to allow for a hollow chamber to permit packing with bone graft to facilitate fusion. This device must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. The titanium alloy interbody cage also comes preassembled with a titanium alloy, built-in rotary locking mechanism. The superior and inferior surfaces of the device have a rough surface to help prevent movement of the device while fusion takes place. When used with screws as integrated fixation, SPIRA-C Integrated Fixation is a stand-alone cervical fixation device. However, this submission seeks to add anchors as another option for integrated fixation. When used with anchors, the SPIRA-C Integrated Fixation System must be used with supplemental fixation.

Indications for Use:
The SPIRA®-C Integrated Fixation System is intended for use as a cervical intervertebral fusion system indicated for use at one or two contiguous levels in the cervical spine (C2-T1), in skeletally mature patients who have had six weeks of non-operative treatment for the following: degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), cervical spondylotic myelopathy, trauma (such as fracture or dislocation), spinal stenosis, deformities or curvatures (such as scoliosis, kyphosis, or lordosis), pseudarthrosis, and failed previous fusion. The device is intended for use with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

When used with screws, SPIRA®-C Integrated Fixation System are standalone interbody fusion devices intended for use at one or two contiguous levels in the cervical spine (C2-T1). When used with anchors, SPIRA®-C Integrated Fixation System is intended for use at one level of the cervical spine with additional supplemental fixation such as posterior cervical screw fixation.

Substantial Equivalence:
The subject SPIRA®-C Integrated Fixation System is substantially equivalent to the following predicate devices:

Primary Predicate(s):
Camber Spine Technologies – SPIRA®-C Open Matrix Cervical Interbody (K172446)

Additional Predicate(s):
Camber Spine Technologies – SPIRA®-C Integrated Fixation System (K193153)
Globus Medical – COALITION MIS® (K173115)
Astura Medical – DOLOMITE Anterior Cervical Stabilization System (K202065)
Glubus Medical – HEDRON Cervical Spacer (K191243, K222270)

The same SPIRA®-C Integrated Fixation System interbody device, previously submitted in K193153 for use with screws, is used in this Premarket 510(k) Notification. The anchors are manufactured from the same Titanium Alloy (Ti-6Al-4V ELI) and cover the same range of sizes (12-18mm). The Indications for Use will be changing for the anchors in this submission when compared to the original SPIRA®-C Integrated Fixation System submission. The anchors will not have standalone indications and require supplemental fixation, similar to the SPIRA®-C Open Matrix Cervical system submitted in K172446. Testing, through the use of Finite Element Analysis (FEA) simulations, shows that the anchors are equivalent to the screw-based construct and has less internal stress than the non-integrated SPIRA®-C Open Matrix cage. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:
An engineering rationale was provided to demonstrate that SPIRA®-C Integrated Fixation System with anchors does not introduce a new worst-case when compared to the previously cleared interbody and screw construct as well as the non-integrated SPIRA®-C cage.

Conclusion:

Based on the engineering rationale and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.