July 11, 2023

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

Re: K230942
Trade/Device Name: SPIRA® Posterior Lumbar Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 25, 2023
Received: June 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,

Brent Showalter -S

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)*
K230942

Device Name
SPIRA® Posterior Lumbar Spacers

Indications for Use *(Describe)*
SPIRA® Posterior Lumbar Spacers (SPIRA®-P Posterior Lumbar Spacer, SPIRA®-T Oblique Posterior Lumbar Spacer, and SPIRA®-TA Posterior Lumbar Spacers) are lumbar interbody fusion devices indicated for use at one or more levels of the lumbosacral spine (L1-S1), as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis), and failed previous fusion (pseudoarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. SPIRA® Posterior Lumbar Spacers are intended to be used with additional FDA-cleared supplementary fixation systems. SPIRA® Posterior Lumbar Spacers are intended for use with an autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone.

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
SPIRA® Posterior Lumbar Spacers
25 June 2023

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

Company Contact: Brooks McAdam
VP of Operations
(484) 427-7060
bmcadam@cambermedtech.com

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

Trade Name: SPIRA® Posterior Lumbar Spacers

Common Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Classification: Class II

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

Panel: Orthopedic

Product Code: MAX

Device Description:
The Camber Spine Technologies SPIRA® Posterior Lumbar Spacers are lumbar interbody fusion devices that have an open matrix design to permit packing with autogenous graft material to facilitate fusion. The subject submission seeks to expand the indications of the existing SPIRA® Posterior Lumbar Spacers (SPIRA®-P and SPIRA®-T) as well as add the subject SPIRA®-TA components to the system. The Camber Spine Technologies SPIRA®-TA Posterior Lumbar Spacer allows the interbody fusion device to be inserted from a transforaminal approach. The superior and inferior surfaces of the device have a rough surface to help prevent movement of the device while fusion takes place. The device contains a rotating pin that allows for articulation to accommodate the surgical approach. Patients with previous non-fusion spinal surgery at the treated level may be treated.

Camber Spine Technologies SPIRA®-TA device body is additively manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F3001-14. The internal device components (locking cap and pivot pin) are manufactured from titanium alloy (Ti-6Al-4V) per ASTM F136.

Indications for Use:
SPIRA® Posterior Lumbar Spacers (SPIRA®-P Posterior Lumbar Spacer, SPIRA®-T Oblique Posterior Lumbar Spacer, and SPIRA®-TA Posterior Lumbar Spacers) are lumbar interbody fusion devices indicated for use at one or more levels of the lumbosacral spine (L1-S1), as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis), and failed previous fusion (pseudoarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. SPIRA® Posterior Lumbar Spacers are intended to be used with additional FDA-cleared supplementary fixation systems. SPIRA® Posterior Lumbar Spacers are intended for use with an autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone.

Substantial Equivalence:
The subject SPIRA® Lumbar Posterior Spacers are substantially equivalent to the following predicate devices:
Primary Predicate:

- Camber Spine Technologies – SPIRA®-T Oblique Posterior Lumbar Spacers, SPIRA®-P Posterior Lumbar Spacers (K210595)

Secondary Predicate:

- 4Web Posterior Spine Truss System™ – TLIF STS (K171351, K143258)
- Globus Medical PATRIOT® Lumbar Spacers – Signature (K072970, K122097, K181357)
- K2M CASCADIA® – TL 3D Interbody System (K172941)
- Pinnacle InFill (41-TLIF convex, 42-TLIF lordotic oblique, 43-TLIF Contour) (K150206, K133721)

When comparing the subject SPIRA®-TA and the primary predicate SPIRA®-T interbody fusion device, the only difference is the curved perimeter of the subject device which is attributed to the surgical approach of the device. This design is most similar to the secondary predicate 4Web Posterior Spine Truss System - Curved (K171351, K143258), with the dimensions falling within the range of the secondary predicate Cascadia TL 3D Interbody System (K172941). The materials of the subject device are identical to those of the primary predicate device. The indications for use of the subject device are similar to those of the primary predicate SPIRA®-T device, with the added indications for deformity, similar to the secondary predicate Globus Medical PATRIOT Lumbar Spacers (K072970, K122097, K181357), and the added indication for pseudoarthrosis. Testing shows that the subject SPIRA®-TA performs equivalent to the SPIRA®-T. Therefore, it is concluded that the subject device demonstrates substantial equivalence to the predicate devices and no new issues of safety and effectiveness have been created.

Performance Testing:
Mechanical testing, including dynamic compression shear, dynamic axial compression, static compression shear, and static axial compression per ASTM F2077, as well as subsidence per ASTM F2267 have been performed on the subject SPIRA® Posterior Lumbar Spacer interbody device. The results have shown them to be substantially equivalent to the predicate interbody devices.

Conclusion:

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