July 12, 2024

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

Re: K234077
Trade/Device Name: SPIRA® Anterior Lumbar Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, PHM
Dated: June 13, 2024
Received: June 13, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234077

Device Name
SPIRA Anterior Lumbar Spacers

Indications for Use *(Describe)*

The Camber Spine Technologies SPIRA® Anterior Lumbar Spacers (SPIRA® Open Matrix ALIF, SPIRA® Open Matrix LLIF and SPIRA®-O Open Matrix Lateral Anterior Lumbar Spacers) are lumbar interbody fusion devices indicated for use at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc discase (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis). spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The SPIRA® Anterior Lumbar Spacers are intended to be used with additional FDA-cleared supplemental fixation systems. The Camber Spine Technologies SPIRA® Anterior Lumbar Spacers system must be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

The Camber Spine Technologies SPIRA-A Integrated Fixation System is indicated for use at one or more levels from L1-S1 as an adjunct to fusion in skeletally mature 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 (pseudarthrosis). 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 nonoperative treatment prior to treatment with the devices. The Camber Spine Technologies SPIRA-A Integrated Fixation System spacers must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. These devices are intended to be used with or without three screws and/or anchors which accompany these implants. These spacers are intended for use with additional FDA-cleared supplemental fixation. In addition, these spacers are intended for stand-alone use in patients with DDD at one or two contiguous levels only when ≤20° lordotic implants are used with three screws per implant. Otherwise, all other configurations of this system are not intended for stand-alone use and must be used with additional FDA-cleared supplemental 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® Anterior Lumbar Spacers
9 July 2024

Company: Camber Spine Technologies
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(484) 427-7060

Company Contact: Brooks McAdam
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901-831-8053

Trade Name: Camber SPIRA® Anterior Lumbar Spacers

Common Name: Intervertebral Fusion Device With Bone Graft, Lumbar
Intervertebral Fusion Device With Integrated Fixation, Lumbar
Intervertebral Fusion Device With Bone Graft, Thoracic

Classification: Class II

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

Panel: Orthopedic

Product Code: MAX, OVD, PHM

Device Description:
The Camber Spine Technologies SPIRA® Anterior 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® Anterior Lumbar Spacers (SPIRA® Open Matrix ALIF and SPIRA® Open Matrix LLIF). Additionally, this submission seeks to expand the anterior lumbar spacer options by adding the subject SPIRA®-O Open Matrix Lateral Anterior Lumbar Spacers components to the SPIRA® Anterior Lumbar Spacers as well as add the SPIRA®-A Integrated Fixation System.

The Camber Spine Technologies SPIRA®-O Open Matrix Lateral Anterior Lumbar Spacers are interbody fusion devices with an open matrix design consisting primarily of spiral support members to permit bone growth (i.e., interbody fusion) throughout the implant. These implants may be inserted from an anterior oblique lateral 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 implants are available in a variety of sizes to accommodate varies patient anatomies.

The Camber Spine Technologies SPIRA®-A Integrated Fixation System is an anterior lumbar interbody fusion device that has an open matrix design to permit packing with autogenous and/or allogenous graft material to facilitate fusion as well as additional fixation options to secure the implant in the disc space. The superior and inferior surfaces of the device have a rough surface to help prevent movement of the device while fusion takes place, and structural arched to help distribute load across the joint space. The device contains three holes to insert bone screws or anchors for integrated fixation, as well as blocking screws to prevent fixation back-out. Patients with previous non-fusion spinal surgery at the treated level may be treated.

Camber Spine Technologies SPIRA® Anterior Lumbar Spacers, SPIRA®-A Integrated Fixation System blocker screws, and bone anchors are additively manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F3001. The SPIRA®-A Integrated Fixation System bone screws are manufactured from titanium alloy (Ti-6Al-4V) per ASTM F136.

Indications for Use:
The Camber Spine Technologies SPIRA® Anterior Lumbar Spacers (SPIRA® Open Matrix ALIF, SPIRA® Open Matrix LLIF and SPIRA®-O Open Matrix Lateral Anterior Lumbar Spacers) are lumbar interbody fusion devices indicated for use at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc discase (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis). spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The SPIRA® Anterior Lumbar Spacers are intended to be used with additional FDA-cleared supplemental fixation systems. The Camber Spine Technologies SPIRA® Anterior Lumbar Spacers system must be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

The Camber Spine Technologies SPIRA-A Integrated Fixation System is indicated for use at one or more levels from L1-S1 as an adjunct to fusion in skeletally mature 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 (pseudarthrosis). 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 nonoperative treatment prior to treatment with the devices. The Camber Spine Technologies SPIRA-A Integrated Fixation System spacers must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. These devices are intended to be used with or without three screws and/or anchors which accompany these implants. These spacers are intended for use with additional FDA-cleared supplemental fixation. In addition, these spacers are intended for stand-alone use in patients with DDD at one or two contiguous levels only when ≤20° lordotic implants are used with three

screws per implant. Otherwise, all other configurations of this system are not intended for stand-alone use and must be used with additional FDA-cleared supplemental fixation.

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

Primary Predicate:

- Camber Spine Technologies – SPIRA® Open Matrix ALIF (K162986, K190483)

Secondary Predicate:

- Camber Spine Technologies – SPIRA® Open Matrix LLIF (K190483)
- Globus Medical - HEDRON IA (K222270, K203278, K191391)
- 4Web - Anterior Spine Truss System – Stand Alone (ASTS-SA) Interbody Fusion Device (K200002)
- CoreLink, LLC – CoreLink® M3™ Stand-Alone Anterior Lumbar System (K180814)
- Globus Medical – CORBEL Spacers (K201087)

The subject SPIRA®-O Open Matrix Lateral Anterior Lumbar Spacer is similar in design and identical in indications for use to the predicate SPIRA® Open Matrix ALIF and SPIRA® Open Matrix LLIF devices (K190483). The subject device SPIRA®-A Integrated is most similar in design and indications for use to the predicate Globus Medical HEDRON IA and CORBEL spacers. The materials of the subject devices are identical to those of the predicate devices. Analysis has shown that the SPIRA®-O devices are not expected to introduce a new worst case compared to the predicate SPIRA® Open Matrix ALIF devices and testing shows that the subject SPIRA®-A Integrated meets or exceeds the values of previously cleared devices. 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:
The following mechanical testing has been performed on the SPIRA®-A Integrated Fixation System: static and dynamic compression shear per ASMT F2077, static and dynamic axial compression per ASTM F2077, subsidence per ASTM F2267, expulsion, static and dynamic bending per ASTM F2193, and anchor impaction testing. Finite Element Analysis and geometric comparisons were conducted on the subject SPIRA®-O devices in comparison to the predicate. The results all tests and analysis have shown the subject devices 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.