June 15, 2021

Camber Spine Technologies, LLC
Donald Guthner
Manager, Regulatory Affairs
501 Allendale Road
King of Prussia, Pennsylvania 19604

Re: K210595
Trade/Device Name: SPIRA®-T Oblique Posterior Lumbar Spacers, SPIRA®-P Posterior Lumbar Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 16, 2021
Received: March 17, 2021

Dear Donald Guthner:

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 L. 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)*

K210595

Device Name
SPIRA®-P Posterior Lumbar Spacers

Indications for Use *(Describe)*

SPIRA®-P Posterior Lumbar Spacers are lumbar interbody fusion devices 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. The device must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The SPIRA®-P Posterior Lumbar Spacers are intended to be used with additional FDA-cleared supplementary fixation systems.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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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)*

K210595

Device Name
SPIRA®-T Oblique Posterior Lumbar Spacers

Indications for Use *(Describe)*

SPIRA®-T Oblique Posterior Lumbar Spacers are lumbar interbody fusion devices 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. The device must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The SPIRA®-T Oblique Posterior Lumbar Spacers are intended to be used with additional FDA-cleared supplementary fixation systems.

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)

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510(k) Summary

Device Trade Name: SPIRA®-T Oblique Posterior Lumbar Spacer
SPIRA®-P Posterior Lumbar Spacer

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

Contact:
Mr. Donald W. Guthner
Manager of Regulatory Affairs
Camber Spine Technologies, LLC
501 Allendale Road
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Date Prepared: March 16, 2021

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Code: MAX

Primary Predicate: Globus HEDRON Lumbar Spacers (K191391)

Reference Predicate(s): 4WEB Posterior Spine Truss System (PSTS) Interbody Fusion Device (K171351)
Camber Spine Technologies Ti-Diagon Oblique TLIF (K172064)
Camber Spine Technologies SPIRA-A Open Matrix ALIF (K190483)

Indications For Use:

SPIRA®-P Posterior Lumbar Spacers are lumbar interbody fusion devices 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. The device must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The SPIRA®-P Posterior Lumbar Spacers are intended to be used with additional FDA-cleared supplementary fixation systems.

SPIRA®-T Oblique Posterior Lumbar Spacers are lumbar interbody fusion devices 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. The device must be used with

autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The SPIRA®-T Oblique Posterior Lumbar Spacers are intended to be used with additional FDA-cleared supplementary fixation systems.

Device Description:

SPIRA Posterior Lumbar Spacers (SPIRA-P Open Matrix PLIF, SPIRA-T Oblique Open Matrix TLIF) are lumbar interbody fusion devices used to provide structural stability following discectomy. SPIRA Posterior Lumbar Spacers have different shapes to accommodate posterior and transforaminal approaches.

Predicate Device:

The subject SPIRA Posterior Lumbar Spacers is substantially equivalent to primary predicate, Globus HEDRON Lumbar Spacers (K191391). Additional predicates were referenced with regards to design inputs, materials, and manufacturing: the 4WEB Posterior Spine Truss System (PSTS) Interbody Fusion Device (K171351), Camber Spine Technologies Ti-Diagon Oblique TLIF (K172064), and Camber Spine Technologies SPIRA-A Open Matrix ALIF (K190483).

Performance Testing Summary:

Testing performed indicate that the SPIRA Posterior Lumbar Spacers are as mechanically sound as predicate devices. Testing included static compression, static compression-shear, dynamic compression, dynamic compression-shear, and subsidence per ASTM F2077-18 and F2267-04. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Substantial Equivalence:

The subject SPIRA Posterior Lumbar Spacers device was demonstrated to be substantially equivalent to primary predicate, Globus HEDRON Lumbar Spacers (K191391). Additional predicates were referenced with regards to design inputs, materials, and manufacturing: the 4WEB Posterior Spine Truss System (PSTS) Interbody Fusion Device (K171351), Camber Spine Technologies Ti-Diagon Oblique TLIF (K172064), and Camber Spine Technologies SPIRA-A Open Matrix ALIF (K190483).

Conclusion:

Camber Spine Technologies has provided sufficient information to demonstrate the SPIRA Posterior Lumbar Spacers are substantially equivalent to primary predicate, the Globus HEDRON Lumbar Spacers (K191391) and additional predicates, the 4WEB Posterior Spine Truss System (PSTS) Interbody Fusion Device (K171351), Camber Spine Technologies Ti-Diagon Oblique TLIF (K172064), and Camber Spine Technologies SPIRA-A Open Matrix ALIF (K190483) with respect to indications, design, materials, function, manufacturing, and/or performance.