September 23, 2019

Camber Spine Technologies
% Matthew Carey
Junior Regulatory Affairs/Quality Consultant
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K190483
Trade/Device Name: SPIRA Open Matrix ALIF and LLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 16, 2019
Received: August 27, 2019

Dear Matthew Carey:

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,

for Ronald P. Jean, Ph.D.
Director (Acting)
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)*
K190483

Device Name
SPIRA Open Matrix ALIF and LLIF

Indications for Use *(Describe)*

SPIRA Open Matrix ALIF

The Camber Spine Technologies SPIRA™ Open Matrix ALIF is 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 nonoperative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Camber Spine Technologies SPIRA™ Open Matrix ALIF is intended to be used with additional FDA-cleared supplementary fixation systems. The Camber Spine Technologies SPIRA™ Open Matrix ALIF system must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

SPIRA Open Matrix LLIF

The Camber Spine Technologies SPIRA Open Matrix LLIF is 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 nonoperative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Camber Spine Technologies SPIRA Open Matrix LLIF is intended to be used with additional FDA-cleared supplementary fixation systems. The Camber Spine Technologies SPIRA Open Matrix LLIF system must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

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

Camber Spine Technologies SPIRA Open Matrix ALIF and LLIF

I. SUBMITTER

Camber Spine Technologies
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Phone: 484.427.7060

Contact Person:
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Date Prepared: 19 September 2019

II. DEVICE

Trade/Device Name:	SPIRA Open Matrix ALIF and SPIRA Open Matrix LLIF
Common or Usual Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Classification Name:	Intervertebral body fusion device
Regulation Number:	21 CFR 888.3080
Regulatory Class:	Class II
Product codes	MAX

III. PREDICATE DEVICES

Primary Predicates:	SPIRA Open Matrix LLIF (K180724) SPIRA Open Matrix ALIF (K162986)
Additional Predicate:	Centinel Spine STALIF TT70, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ (K150643)
Reference Predicate:	SPIRA-C Open Matrix Cervical Interbody, Camber Spine Technologies (K172446)

IV. DEVICE DESCRIPTION

SPIRA Open Matrix ALIF is an interbody fusion device with an open matrix design consisting primarily of arched support members to permit bone growth (i.e., interbody fusion) throughout the implant, SPIRA Open Matrix ALIF. With the exception of the perimeter, all surfaces have a roughened texture to help prevent movement of the device.

SPIRA Open Matrix LLIF is an interbody fusion device with an open matrix design consisting primarily of spiral support members to permit bone growth (i.e., interbody fusion) throughout the implant, SPIRA-L Open Matrix LLIF

The purpose of this submission is the addition of the allogenic bone graft indication to both SPIRA ALIF and SPIRA LLIF devices that have been cleared under K162986 and K180724 respectively.

Indications for Use:

SPIRA™ Open Matrix ALIF

The Camber Spine Technologies SPIRA™ Open Matrix ALIF is 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. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Camber Spine Technologies SPIRA™ Open Matrix ALIF is intended to be used with additional FDA-cleared supplementary fixation systems. The Camber Spine Technologies SPIRA™ Open Matrix ALIF system must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

SPIRA™ Open Matrix LLIF

The Camber Spine Technologies SPIRA Open Matrix LLIF is 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. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Camber Spine Technologies SPIRA Open Matrix LLIF is intended to be used with additional FDA-cleared supplementary fixation systems. The Camber Spine Technologies SPIRA Open Matrix LLIF system must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject SPIRA Open Matrix LLIF and SPIRA Open Matrix ALIF device was demonstrated to be substantially equivalent to primary predicates SPIRA Open Matrix LLIF (K180724) and SPIRA Open Matrix ALIF (K162986) with respect to indications, design, materials, function, manufacturing, and/or performance.

VI. PERFORMANCE DATA

A Finite Element Analysis (FEA) was performed to evaluate the effects of design changes to the SPIRA Open Matrix LLIF on the worst-case implant and determine if the design changes created new worst-case scenarios. The testing performed was static axial compression, compression shear, and surface area comparison (subsidence and expulsion equivalence). Testing proved that the new design did not create a new worst-case under any testing condition.

VII. CONCLUSION

Camber Spine Technologies provided sufficient information to demonstrate the SPIRA Open Matrix LLIF and SPIRA Open Matrix ALIF device is substantially equivalent to predicates SPIRA Open Matrix LLIF (K180724), SPIRA Open Matrix ALIF (K162986), and Centinel Spine STALIF TT70, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ (K150643) with respect to indications, design, materials, function, manufacturing, and performance.