September 15, 2017

Dear Mr. Eggleton:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Device Name
Ti-Diagon Oblique TLIF

Indications for Use (Describe)

The Camber Spine Technologies Ti-Diagon® Oblique TLIF is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Camber Spine Technologies Ti-Diagon® Oblique TLIF is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach.

Camber Spine Technologies Ti-Diagon® Oblique TLIF implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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."

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASstaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) Summary

Device Trade Name: Ti-Diagon Oblique TLIF

Manufacturer: Camber Spine Technologies
418 E. Lancaster Ave.
Wayne, PA 19087

Contact: Mr. Daniel A. Pontecorvo
CEO
Phone: 484.427.7060

Prepared by: Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800
jeggleton@mcra.com

Date Prepared: September 7, 2017

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: MAX

Primary Predicate: Camber Spine Technologies TLS 5.0 Interbody Cage (K121254)

Additional Predicate(s): Camber Spine Technologies Diagon Oblique Cage (K134038), and Aurora Spine Interbody Fusion System (K133967)

Reference Device: Rhausler Plage™ Anterior Cervical Fusion System (K111272)

Indications For Use:
The Camber Spine Technologies Ti-Diagon Oblique TLIF is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Camber Spine Technologies Ti-Diagon Oblique TLIF is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach. Camber Spine Technologies Ti-
Diagon Oblique TLIF implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

**Device Description:**
The Camber Spine Technologies Ti-Diagon Oblique TLIF is an interbody fusion device with a hollow chamber to permit packing of autologous bone graft in order to facilitate fusion. The inferior and superior surfaces of the Ti-Diagon Oblique TLIF have a rough texture, as the result of a photochemical etching process, to help prevent movement of the device.

**Predicate Device:**
The subject Ti-Diagon Oblique TLIF device is substantially equivalent to predicates Camber Spine Technologies TLS 5.0 Interbody Cage (K121254), Camber Spine Technologies Diagon Oblique Cage (K134038), and Aurora Spine Interbody Fusion System (K133967) with respect to indications, design, materials, function, manufacturing, and/or performance. Additional comparisons were made to the reference device Rhausler Plage™ Anterior Cervical Fusion System (K111272).

**Performance Testing Summary:**
Testing performed indicates that the Ti-Diagon Oblique TLIF is as mechanically sound as predicate devices. Testing included static compression, static compression shear, dynamic compression, dynamic compression shear, expulsion, and subsidence per ASTM F2077-14 and F2267-04. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

**Substantial Equivalence:**
The subject Ti-Diagon Oblique TLIF device was demonstrated to be substantially equivalent to predicates Camber Spine Technologies TLS 5.0 Interbody Cage (K121254), Camber Spine Technologies Diagon Oblique Cage (K134038), and Aurora Spine Interbody Fusion System (K133967) with respect to indications, design, materials, function, manufacturing, and/or performance. Additional comparisons were made to the reference device Rhausler Plage™ Anterior Cervical Fusion System (K111272).

**Conclusion:**
Camber Spine Technologies provided sufficient information to demonstrate the Ti-Diagon Oblique TLIF is substantially equivalent to predicates Camber Spine Technologies TLS 5.0 Interbody Cage (K121254), Camber Spine Technologies Diagon Oblique Cage (K134038), and Aurora Spine Interbody Fusion System (K133967) with respect to indications, design, materials, function, manufacturing, and/or performance. Additional comparisons were made to the reference device Rhausler Plage™ Anterior Cervical Fusion System (K111272).