DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 18, 2017

Camber Spine Technologies
% Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
MCRA, LLC
1331 H St NW, 12th Fl
Washington, District of Columbia 20005

Re: K162121
Trade/Device Name: Siconus™ SI Joint Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: January 11, 2017
Received: January 13, 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 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 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,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162121

Device Name
Camber Spine Technologies
SICONUS™ SI Joint Fixation System

Indications for Use *(Describe)*
The SICONUS™ SI Joint Fixation System is intended to provide fixation and stabilization of large bones, including the sacrum and ilium. It is intended for use in skeletally mature patients as an adjunct to sacroiliac joint fusion in the treatment of degenerative sacroiliitis, or sacroiliac joint disruptions.

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.

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510(k) Summary

Trade Name	Siconus™ SI Joint Fixation System
Common Name	SI Joint Screw System / SI Joint Fixation System
Manufacturer	Camber Spine Technologies 418 E. Lancaster Ave. Wayne, PA 19087
Contact	Justin Eggleton Senior Director, Spine Regulatory Affairs Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 Phone: (202) 552-5800 jeggleton@mcra.com
Prepared By	Mr. Damian Heinz, PE Senior Principal Engineer Institute of Musculoskeletal Science and Education 418 E. Lancaster Ave. Wayne, PA 19087 Phone: 484.420.4286 x307 Fax: 484.318.8031
Date Prepared	January 17, 2017
Device Class	Class II
Classification Name	Smooth or threaded metallic bone fixation fastener
Classification Number	21 CFR §888.3040
Classification Panel:	Orthopedic
Product Code	OUR
Reason for 510(k)	New Device
Predicate Device	Xtant (X-Spine) Silex™ SI Joint Fusion System (K123702) Synthes Cannulated Screw (K021932) Zyga SImmetry Sacroiliac Joint Fusion System (K102907)

Indications:

The Siconus™ SI Fixation System is intended to provide fixation and stabilization of large bones, including the sacrum and ilium. It is intended for use in skeletally mature patients as an adjunct

to sacroiliac joint fusion in the treatment of the degenerative sacroiliitis, or sacroiliac joint disruptions.

Device Description:

The Camber Spine Technologies Siconus™ SI Joint Fixation System is a partially threaded, fully cannulated, bone fixation device that has a threaded distal end with a buttress-style profile in order to secure the device in cancellous bone. The proximal head of the device has a conical shape that provides axial compression of the bones across the sacroiliac joint in order to promote fusion. The head of the device also contains a tapered thread that allows the device to advance into hard cortical bone by displacing material, while also maintaining compression and preventing movement of the device. The proximal head and distal thread is connected by a smooth shaft. In the large version of the device, this shaft contains a slot along the axis to permit packing with bone graft to facilitate fusion.

Predicate Device:

The predicate devices selected for this 510(k) are the X-spine Silex™ SI Joint Fusion System (K123702), Synthes Cannulated Screw (K021932), and Zyga SImmetry Sacroiliac Joint Fusion System (K102907). The subject Siconus™ SI Fixation device is substantially equivalent to the predicate devices with respect to indications, intended use, design, function, and performance.

Substantial Equivalence:

The Siconus™ SI Joint Fixation System is considered to be equivalent in safety and effectiveness (i.e., “substantially equivalent”) as the predicates, the X-spine Silex™ SI Joint Fusion System (K123702), Synthes Cannulated Screw (K021932), and Zyga SImmetry Sacroiliac Joint Fusion System (K102907). All systems utilize comparable surgical techniques. All systems include implants and instruments that are manufactured using biocompatible materials with a long history of use in orthopedic surgery.

Performance Testing:

Mechanical tests performed indicate that the Siconus™ SI Joint Fixation System performs equally or better as compared to the predicate devices. Testing included static torsion, static bending, dynamic bending, and screw thread pullout per ASTM F2193-02 and ASTM F543-07. The results of these tests demonstrate that the subject device is equivalent or exceeds the acceptance criteria defined by equivalent tests performed on the predicate devices.

Conclusion:

Camber Spine Technologies has provided sufficient information to demonstrate the Siconus™ SI Joint Fixation System is substantially equivalent to the predicate X-Spine Silex™ Sacroiliac Fusion Device (K123702), Synthes Cannulated Screw (K021932), and Zyga SImmetry Sacroiliac Joint Fusion System (K102907) with respect to indications, intended use, design, function, and performance.