October 27, 2018

Camber Spine Technologies LLC
% Manjusha Bharadwaj
Regulatory/Quality Consultant
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K180980
Trade/Device Name: ORTHROS™ Posterior Stabilization System; ORTHROS™ MIS Posterior Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: September 20, 2018
Received: September 25, 2018

Dear Manjusha Bharadwaj:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180980

Device Name
ORTHROS™ MIS Posterior Stabilization System

Indications for Use *(Describe)*
The ORTHROS™ MIS Posterior Stabilization System, when used in a posterior percutaneous approach is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1-S1/ Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, ORTHROS™ MIS Posterior Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L-3- sacrum/ilium.

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.

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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
PRAStaff@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."

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In addition, the ORTHROS™ Posterior Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

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510(k) SUMMARY

Camber Spine Technologies ORTHROS™ Posterior Stabilization System

Camber Spine Technologies ORTHROS™ MIS Posterior Stabilization System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Camber Spine Technologies
418 E. Lancaster Ave.
Wayne, PA 19087
Phone: 484-427-7060

Contact Person:
Thomas Zamorski
Project Engineer
The Institute for Musculoskeletal Science and Education
418 E. Lancaster Ave.
Wayne, PA 19087
Phone: 484-420-4286
Fax: 484-318-8031
Email: tzamorski@imseinstitute.org

Manjusha Bharadwaj
Regulatory/Quality Consultant
RQMIS Inc.
110 Haverhill Rd., Suite 526
Amesbury, MA 01913
Phone: 978-358-7307
Facsimile: 978-447-0206
Email: manjushabharadwaj@rqmis.com

Date Prepared: September 17, 2018

Name of Device and Name/Address of Sponsor

Trade Name: ORTHROS™ Posterior Stabilization System / ORTHROS™ MIS Posterior Stabilization System
Camber Spine Technologies
418 E. Lancaster Ave.
Wayne, PA 19087

Common or Usual Name

Device Type: Thoracolumbosacral Pedicle Screw System

Classification Name

21 CFR 888.3070 Thoracolumbosacral pedicle screw system

Device Class: Class II

Product Codes: NKB

Reason for 510(k) Submission

This 510(k) is being submitted to address the MIS intended use of these implants in their labelling. The new intended use and the system components for MIS system including the "long towers" was introduced as part of note to file for the existing 510k K133366, but a recent review of the regulatory strategy by an outside regulatory council resulted in a decision to file a 510k for the addition of this intended use. This traditional 510(k) also documents the changes to the ORTHROS™ Posterior Stabilization System that have occurred since its clearance in K133366. These devices include cross links, anti-rotation rods, solid reduction screws, and instrumentation. The additions and minor modifications to the ORTHROS™ Posterior Stabilization System, subject to applicant's risk management system, do not change the previously cleared ORTHROS™ Posterior Stabilization System (K133366) indications for use, contraindications, warnings, or precautions, and do not raise new issues of safety or effectiveness. Camber Spine Technologies believes that the ORTHROS™ MIS Posterior Stabilization System is substantially equivalent to the primary predicate, Camber Spine Technologies ORTHROS™ Posterior Stabilization System (K133366), and the additional predicate Orthofix Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K171082).

Predicate Devices

Primary Predicate: Camber Spine Technologies ORTHROS™ Posterior Stabilization System (K133366)

The subject ORTHROS™ MIS Posterior Stabilization System was demonstrated to be substantially equivalent to the following predicate devices: Camber Spine Technologies ORTHROS™ Posterior Stabilization System (K133366) and Orthofix Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K171082) with respect to indications, design, materials, function, manufacturing, and/or performance.

Intended Use / Indications for Use

The ORTHROS™ MIS Posterior Stabilization System, when used in a posterior percutaneous approach is intended to provide immobilization and stabilization of spinal

segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1-S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal tumor, and failed previous fusion (pseudarthrosis). In addition, ORTHROS™ MIS Posterior Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L-3-sacrum/ilium.

The ORTHROS™ Posterior Stabilization System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1-S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). In addition, the ORTHROS™ Posterior Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

Technological Characteristics

The ORTHROS™ Posterior Stabilization System is a multiple component, posterior stabilization system which consists of a variety of shapes and sizes of rods, monoaxial screws, polyaxial screws, cannulated polyaxial screws, reduction screws, cannulated reduction screws, locking caps, locking set screws, cross links, and associated manual surgical instruments. The ORTHROS™ Posterior Stabilization System is designed to provide immobilization and stabilization of spinal segments as an adjunct to fusion in skeletally mature patients. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws are intended for posterior and anterior use. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking Caps and Locking Set Screws are used to connect the screws to the rods. All implants are composed of Titanium Alloy (TAV), as specified in ASTM F136.

The ORTHROS™ MIS Posterior Stabilization System is a multiple component, minimally invasive posterior stabilization system which consists of a variety of shapes and sizes of rods, cannulated percutaneous/MIS polyaxial screws, locking set screws, and associated manual surgical instruments. The ORTHROS™ MIS Posterior Stabilization System is designed to provide

immobilization and stabilization of spinal segments as an adjunct to fusion in skeletally mature patients. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. The MIS polyaxial screws are intended for posterior use. Locking Set Screws are used to connect the screws to the rods. All implants are composed of Titanium Alloy (TAV), as specified in ASTM F136. The ORTHROS™ MIS System also utilizes select instrumentation from the ORTHROS™ Posterior Stabilization System.

Performance Data

Testing performed indicates that the ORTHROS™ MIS Posterior Stabilization System is as mechanically sound as predicate devices. Testing included static compression, dynamic compression, and static torsion per ASTM F1717-15. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Testing Performed

1. Static Axial Compression
2. Dynamic Axial Compression
3. Static Axial Torsion
4. Screw Pullout per ASTM F543
5. Static Axial Grip Test per ASTM F1798
6. Torsional Grip Test per ASTM F1798

Substantial Equivalence

The ORTHROS™ MIS Posterior Stabilization System is substantially equivalent to the original ORTHROS™ Posterior Stabilization System (K133366) and the Orthofix Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K171082). The ORTHROS™ MIS Posterior Stabilization System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the ORTHROS™ MIS Posterior Stabilization System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrates that the ORTHROS™ MIS Posterior Stabilization System is substantially equivalent to the original ORTHROS™ Posterior Stabilization System (K133366).