Camber Spine Technologies LLC
% Barry Sands
President
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

October 22, 2019

Re: K191584
Trade/Device Name: FORTICO Anterior Cervical Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 17, 2019
Received: September 23, 2019

Dear Mr. Sands:

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)*
K191584

Device Name
FORTICO Anterior Cervical Fixation System

Indications for Use *(Describe)*
The FORTICO Anterior Cervical Fixation System (Fortico Plate and Screws) is intended for anterior screw fixation to the cervical spine (C2-T1) in skeletally mature patients for the following indications: degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (such as fracture or dislocation), spinal stenosis, deformities or curvatures (such as scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and failed previous fusion.

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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K191584: 510(k) Summary

Device Trade Name: FORTICO Anterior Cervical Fixation System

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

Contact: Rami Hamzey
Project Engineer
The Institute for Musculoskeletal Science & Education (IMSE)
Phone: 484.482.6567

Prepared by: Rami Hamzey

Date Prepared: 16 September 2019

Classifications: 21 CFR §888.3060, Spinal intervertebral body fixation orthosis

Class: II

Product Code: KWQ

Primary Predicate: Medos International Sárl Uniplate 2 Anterior Cervical Plate System (K132324)

Additional Predicate(s): Globus Medical Inc. XTEND Anterior Cervical Plate System (K092146, K181846),

Medtronic International ZEVO™ Anterior Cervical Plate System (K182885, K141632)

Indications for use:
The FORTICO Anterior Cervical Fixation System (Fortico Plate and Screws) is intended for anterior screw fixation to the cervical spine (C2-T1) in skeletally mature patients for the following indications: degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (such as fracture or dislocation), spinal stenosis, deformities or curvatures (such as scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and failed previous fusion.

Device Description:
The FORTICO Anterior Cervical Fixation System is a cervical plating system that consists of a cervical plate that includes bone screw holes and blocking mechanisms to prevent screw back-out.

Predicate Device(s):
The FORTICO Anterior Cervical Fixation System was demonstrated to be substantially equivalent in design to the Medos International Sárl Uniplate® 2 Anterior Cervical Plate System (K132324), the Globus

Medical Inc. XTEND Anterior Cervical Plate System (K092146, K181846), and Medtronic International's ZEVO™ Anterior Cervical Plate System (K182885, K141632).

Performance Testing Summary:
Testing performed indicates that the FORTICO Anterior Cervical Fixation System is as mechanically sound as similar devices which are legally marketed for sale in the United States. Testing included static and dynamic compression bending and static torsion of the FORTICO Anterior Cervical Fixation System per ASTM F1717. The results are provided for the appropriate governing body to assess against legally marketed products in the United States with identical indications.

Substantial Equivalence:
Camber Spine asserts that the subject FORTICO Anterior Cervical Fixation System is substantially equivalent to the Medos International Sárl Uniplate® 2 Anterior Cervical Plate System (K132324), Globus Medical Inc. XTEND Anterior Cervical Plate System (K092146, K181846), and the Medtronic International ZEVO™ Anterior Cervical Plate System (K182885, K141632) with respect to indications, design, materials, function, manufacturing, and/or performance.

Conclusion:
Camber Spine provided ample information to demonstrate that the FORTICO Anterior Cervical Fixation System is substantially equivalent to the Medos International Sárl Uniplate 2 Anterior Cervical Plate System (K132324), Globus Medical Inc. XTEND Anterior Cervical Plate System (K092146, K181846), and the Medtronic International ZEVO™ Anterior Cervical Plate System (K182885, K141632) with respect to indications, design, materials, function, manufacturing, and/or performance.