Traditional 510(k) Summary

as required by section 807.92(c).

Camber Spine Technologies
Coveris Cage
K 133529

Revised	March 20, 2014
Submitter:	Camber Spine Technologies 90 S. Newtown Street Rd., Suite #10 Newtown Square, PA 19073
Contact Person	Dan Pontecorvo President Phone: 484-420-4219 Fax: (484) 318-8031 Email: delvalsyn@comcast.net
Trade Name	Camber Spine Coveris Cage
Common Name	Intervertebral Body Fusion Device
Device Class	Class II
Classification Name and Number	Intervertebral fusion device with bone graft, cervical 21 CFR 888.3080
Classification Panel:	Orthopedic
Product Code	ODP
Reason for 510k	New Device
Predicate Devices	Corelink Foundation Cage (K 073440), Nexxt Honour Spacer (K120345) & Spinal Elements Crystal (K073351)
Device Description	The Camber Spine Coveris Cage series of intervertebral body fusion devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. They are designed to be used in conjunction with supplemental spinal fixation instrumentation.

	The series is comprised of cages of various fixed heights and shapes for placement in the cervical spine. Each cage has a hollow center to allow placement of graft material inside of the cage. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion. The Coveris Cage of intervertebral body fusion devices are made from the PEEK radiolucent material with embedded tantalum x-ray markers as specified in ASTM F2026 and ASTM F560, respectively.
Implants	The Implant will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10-6 per ISO 17665.

Intended Use	When used as a cervical intervertebral fusion device, the Coveris Cage is indicated for use at one level in the cervical spine, from C3-C7, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems (such as anterior cervical plating systems, or posterior systems) cleared for use in the cervical spine.

Materials:	The implant is manufactured from ASTM2026 Solvay Zeniva ZA-500 implant grade Polyetheretherketone (PEEK)

Statement of Technological Comparison	Camber Spine Coveris Cage and its predicate devices have the same indications for use, similar design, and test results. Both devices are manufactured using materials with a long history of use in orthopaedic implants.

Nonclinical Test Summary	The following tests were performed to demonstrate that the Camber Spine Coveris Cage is substantially equivalent to other predicate devices. • Static and Dynamic Compression Test per ASTM F2077 • Static and Dynamic Compression Shear ASTM F2077 • Static and Dynamic Torsional ASTM F2077 • Subsidence Test per ASTM F2267 • Wear Debris ASTM F2077 and ASTM F1877 • Static Expulsion Test The results of these studies showed that the Coveris Cage met the acceptance criteria.
Clinical Test Summary	No clinical tests were performed.

Conclusion	The Camber Spine Coveris Cage is substantially equivalent to its predicate devices. This conclusion is based upon the fact the Coveris Cage and its predicate devices have the same indications for use, have a similar design and technical characteristics, similar test results, and any differences do not raise question of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

Camber Spine Technologies
Mr. Daniel Pontecorvo
President & CEO
90 South Newtown Street Road, Suite 10
Newtown Square, Pennsylvania 19073

Re: K133529
Trade/Device Name: Coveris Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 10, 2014
Received: February 18, 2014

Dear Mr. Pontecorvo:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Lori A. Wiggins

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

Enclosure

Indications for Use

510(k) Number: K133529

Device Name: Coveris Cage

Indications for Use:

When used as a cervical intervertebral fusion device, the Coveris devices are indicated for use at one level in the cervical spine, from C3-C7, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation (such as anterior cervical plating systems, or posterior systems) systems cleared for use in the cervical spine.

Prescription Use X **AND/OR** **Over-the-counter** _____
(Part 21 CFR 801 Subpart D)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices