



Food and Drug Administration
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Camber Spine Technologies
% Margeaux Rogers
Senior Associate, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

July 13, 2017

Re: K170550
Trade/Device Name: Coveris Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: June 22, 2017
Received: June 23, 2017

Dear Ms. Rogers:

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,

Mark N. Melkerson -S

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 (if known)

K170550

Device Name

Coveris Cervical Cage System

Indications for Use (Describe)

When used as a cervical intervertebral fusion device, the Coveris devices are indicated for use at one or two contiguous levels in the cervical spine, from C2-T1, 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 or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and with supplemental fixation (such as anterior cervical plating systems, or posterior systems) systems cleared for use in the cervical spine.

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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510(k) Summary

Device Trade Name: Coveris Cervical Cage System

Manufacturer:
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Wayne, PA 19087

Contact:
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Date Prepared: February 23, 2017

Classification: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: ODP

Indications For Use:

When used as a cervical intervertebral fusion device, the Coveris devices are indicated for use at one or two contiguous levels in the cervical spine, from C2-T1, 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 or allogenic bone graft composed of cancellous and/or corticocancellous bone graft and with supplemental fixation (such as anterior cervical plating systems, or posterior systems) systems cleared for use in the cervical spine.

Device Description:

The Camber Spine Coveris Cervical 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. There are different cages designed for specific regions of the spine and approaches to the 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 Cervical 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.

Predicate Device:

The primary predicate is the Coveris Cervical Cage System (K133529). The Medtronic Anatomic PEEK PTC Cervical Fusion System (K160528) is an additional predicate. The subject Coveris Cervical Cage System is substantially equivalent to the previously cleared Coveris Cervical Cage System (K133529) with respect to design, function and materials and predicate Medtronic Anatomic PEEK PTC Cervical Fusion System (K160528) with respect to indications, design, function, and materials.

Substantial Equivalence:

The Coveris Cervical Cage System and predicate Medtronic Anatomic PEEK PTC Cervical Fusion System (K160528) are similar in design, material, and indicated use, and are both cleared devices. They do differ in that the Medtronic Anatomic PEEK PTC Cervical Fusion System is indicated for use with allogenic bone graft at one or two contiguous levels. A comprehensive, clinical literature review has been conducted to investigate the risks and benefits associated with using allogenic bone graft with the Coveris Cervical Cage System and mutli-level use. The clinical literature suggests that there is a positive benefit associated with allograft and use at two contiguous levels with minimal risk.

Nonclinical Performance Testing:

Comprehensive, clinical literature review data have been provided to investigate the risks and benefits associated with using allogenic bone graft with the Coveris Cervical Cage System and use at two contiguous levels. Static compression and static torsion testing were performed per ASTM F2077.

Conclusion:

The Coveris Cervical Cage System has been modified to expand the indications to permit use with allograft and use at two contiguous levels, C2-T1. The 510(k) demonstrates substantial equivalence to predicate devices.