



Food and Drug Administration
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Cardinal Spine, LLC
% Kevin Thomas, Ph.D.
Vice President and Director, Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

February 11, 2016

Re: K152568

Trade/Device Name: C-VBR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: PLR
Dated: January 12, 2016
Received: January 13, 2016

Dear Dr. Thomas:

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" (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 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 yours,

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)

K152568

Device Name

C-VBR

Indications for Use (Describe)

C-VBR is a vertebral body replacement device indicated for use in the cervical spine (spanning C2-T1 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The C- VBR System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.

These implants are intended for use with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The C-VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

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
Cardinal Spine, LLC
C-VBR

January 12, 2016

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	C-VBR
Common Name:	Vertebral body replacement device
Classification Name:	Spinal intervertebral body fixation orthosis
Classification Regulations:	21 CFR 888.3060, Class II
Product Code:	PLR
Classification Panel	Orthopedic and Rehabilitation Devices Panel
Reviewing Branch	Anterior Spine Devices Branch (ASDB)

PREDICATE DEVICE INFORMATION

Primary predicate device:
STGC, Cardinal Spine LLC, K121176.

Additional predicate devices:
STGC-Lordotic, Cardinal Spine LLC, K142030; and
NuVasive® X-Core® Mini Cervical Expandable VBR System, K151651.

INTENDED USE

C-VBR is a vertebral body replacement device indicated for use in the cervical spine (spanning C2-T1 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The C- VBR System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.

These implants are intended for use with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The C-VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

DEVICE DESCRIPTION

C-VBR is a vertebral body replacement device manufactured from titanium alloy (Ti-6Al-4V), and is available in a variety of sizes to suit the individual anatomic and clinical circumstances of each patient. C-VBR is a single-piece device manufactured using electrical discharge machining, having a trapezoidal cross section with a hollow interior to accommodate the placement of autograft or allograft bone. Intended for placement via an anterior approach, C-VBR is to be used in combination with supplemental fixation indicated for use in the cervical spine. C-VBR is provided with superior and inferior endplates that are either parallel (no lordosis) or angled to provide intrinsic lordosis (9.6° or 11.5°), and with various heights from 16 mm to 72 mm.

EQUIVALENCE TO MARKETED DEVICES

Cardinal Spine, LLC has submitted information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, C-VBR is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

STGC-Lordotic, Cardinal Spine LLC, K142030;

STGC, Cardinal Spine LLC, K121176; and

NuVasive® X-Core® Mini Cervical Expandable VBR System, K151651.

The primary predicate device is K121176. The additional predicate devices are K142030 and K151651.

The subject device and the predicate devices are intended to be used to provide support after resection or removal of a damaged, collapsed, or unstable vertebral body. The subject device and predicate devices are placed within the area of the resected vertebral body, in combination with autograft or allograft, and are functionally complemented by supplemental internal fixation indicated for use in the spine. The subject device consists of a range of sizes of devices from K121176 and K142030 that are appropriate for use as vertebral body replacement in the cervical spine (spanning C2 to T1 vertebral bodies). The subject device does not include any size that was not cleared previously in K121176 or K142030. The design, materials, and functional characteristics of the subject device and the predicate devices are identical. All of the subject device components are manufactured using the same materials and manufacturing processes as used for the previously cleared predicate devices in K121176 and K142030.

The subject device and the predicate devices are surgically implanted with common generic instruments used for accessing the anterior spine, distracting the interspace, performing disk and vertebral body resections as indicated, packing the selected implant with autogenous bone graft, placing the implant, and subsequent surgical closure. Sizing instruments are provided to assist in measuring corpectomy width and end-plate depth for selection of the optimum implant. The subject device sizing instruments are provided in two (2) sizes that correspond to the endplate sizes (footprint) of the subject device, and are identical to instruments included in K142030.

All of the subject device components, and all of the K121176 and K14203 predicate components, are provided to the end-user nonsterile with validated sterilization instructions.

The subject device has the same indications for use as the reference predicate device K151651.

DISCUSSION OF NONCLINICAL AND CLINICAL DATA SUBMITTED

Nonclinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included dimensional analysis, engineering analysis, and performance testing as described in the standards ASTM F2077 *Test Methods for Intervertebral Body Fusion Devices* (static compression, dynamic compression, static torsion, dynamic torsion) and ASTM F2267 *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression* (subsidence). Static expulsion testing also was performed.

The subject device comprises a subset of the range of physical dimensions of the K121176 and K14203 predicate devices, and the subject device and the corresponding predicate devices have identical design characteristics. The range of sizes of the subject device includes the predicate device sizes that were determined to represent the worst-case for mechanical performance testing

of the predicate devices in K121176 and K142030. Therefore the mechanical performance testing provided previously in K121176 and K142030 are applicable to the subject device. The mechanical testing data demonstrated that the compressive strength, torsional strength, and expulsion resistance of the subject device are adequate to meet the clinical requirements of the intended use as a cervical vertebral body replacement device.

Clinical data submitted in this premarket notification included a review of the results of a series of 97 patients treated with a total of 103 C-VBR devices with an average follow-up period of 14.2 months. The safety of the subject C-VBR device was demonstrated by the fact that there were no device-related complications and no device-related revision surgeries. The effectiveness of the C-VBR device was demonstrated by the improvement in the Nurick Classification scores (mobility restriction caused by cervical myelopathy), maintenance or improvement in cervical sagittal alignment demonstrated by Cobb angle measurements, no significant subsidence of the implants, and radiographic evidence of fusion.

CONCLUSION

The data included in this submission demonstrate that the subject device is substantially equivalent to the predicate devices listed above.

Overall, the subject device has the following similarities to the predicate devices:

- has the intended use to provide support after resection or removal of a damaged, collapsed, or unstable vertebral body;
- has the same indications for use as the reference predicate device K151651;
- uses the same operating principle;
- comprises a subset of the range of sizes of the K121176 and K142030 predicate devices;
- each subject device component has the identical design as the corresponding K121176 and K142030 predicate component;
- are manufactured using the same materials and manufacturing processes; and
- are provided to the end-user nonsterile to be sterilized using the same processes.