DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 23, 2015

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

Re: K142030
Trade/Device Name: STGC-Lordotic
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: December 22, 2014
Received: December 23, 2014

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142030

Device Name
STGC-Lordotic

Indications for Use *(Describe)*
STGC-Lordotic is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture). STGC-Lordotic is intended to be used with autograft or allograft in combination with supplemental fixation indicated for use in the thoracolumbar 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Cardinal Spine, LLC
STGC-Lordotic
K142030

December 22, 2014

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	STGC-Lordotic
Common Name:	Vertebral body replacement device
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Classification Regulations:	21 CFR 888.3060, Class II
Product Code:	MQP
Classification Panel	Orthopedic and Rehabilitation Devices Panel
Reviewing Branch	Anterior Spine Devices Branch (ASDB)

INDICATIONS FOR USE

STGC-Lordotic is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture). STGC-Lordotic is intended to be used with autograft or allograft in combination with supplemental fixation indicated for use in the thoracolumbar spine.

DEVICE DESCRIPTION

STGC-Lordotic 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. STGC-Lordotic 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, STGC-Lordotic is to be used in combination with supplemental fixation indicated for use in the thoracolumbar spine. STGC-Lordotic is provided with 8.2° to 11.5° of endplate angulation (lordosis). STGC-Lordotic is provided non-sterile to the end user.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included: performance testing, engineering analysis and dimensional analysis. Performance testing to demonstrate substantial equivalence included methods 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 performance data included in this submission demonstrate substantial equivalence to the predicate device K121176 and K003043.

Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

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

STGC, Cardinal Spine LLC, K121176,

MaxFuse VBR System, Pioneer Surgical Technology, Inc., K131724, and

Surgical Titanium Mesh System, DePuy AcroMed, K003043.

The primary predicate device is K121176.

The intended use, design, materials, and functional characteristics of the STGC-Lordotic and the predicate device STGC are substantially the same. The subject device and the predicate device STGC encompass a similar range of physical dimensions, and have similar design characteristics. The subject device and the predicate device MaxFuse VBR System also encompass a similar range of physical dimensions including the lordosis intrinsic to the devices. Any differences in the technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

The subject and predicate devices all are intended to be used to provide support after resection or removal of a damaged, collapsed, or unstable vertebral body due to tumor, fracture, or other disease. The subject device and predicate devices are placed within the area of removed or resected spine and are functionally complemented by supplemental internal fixation. The subject device and the predicate devices are intended to be used with bone graft.

CONCLUSION
The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Overall, STGC-Lordotic has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- is to be sterilized using the same processes.