

**510(k) Summary  
Cardinal Spine, LLC**

AUG 17 2012

**STGC**

**K121176**

July 27, 2012

**ADMINISTRATIVE INFORMATION**

Manufacturer Name	Cardinal Spine, LLC 12307 Old LaGrange Road, Suite 105 Louisville, KY 40245 Telephone: +1 (502) 777-4788 Fax: +1 (502) 245-5768
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Official Contact	Natasha Lonnon Vice President
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Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: kthomas@paxmed.com flarson@paxmed.com
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**DEVICE NAME AND CLASSIFICATION**

Trade/Proprietary Name:	STGC
Common Name:	Vertebral body replacement device
Classification Name:	Spinal Vertebral Body Replacement Device

Classification Regulations:	21 CFR 888.3060, Class II
Product Code:	MQP

Classification Panel	Orthopedic and Rehabilitation Devices Panel
Reviewing Branch	Orthopedic Spine Devices Branch

## INTENDED USE

The STGC 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). The STGC is intended to be used with autograft or allograft in combination with supplemental fixation indicated for use in the thoracolumbar spine.

## DEVICE DESCRIPTION

The STGC 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. The STGC 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, the STGC is to be used in combination with supplemental fixation indicated for use in the thoracolumbar spine.

## 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 is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

- DePuy AcroMed, Surgical Titanium Mesh™ System, K003043;
- Synthes (USA), Synthes SynMesh™ Spacer, K003275; and
- LDR Spine USA, LDR Spine Cervical Interbody Fusion System, K091088.

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, and are intended to be used with bone graft. The subject and predicate devices encompass a similar range of physical dimensions and are made of the same or similar titanium alloy materials. Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Performance testing was conducted to demonstrate substantial equivalence and included methods described in ASTM F2077 (static and dynamic compression, static and dynamic torsion), ASTM F2267 (subsidence), and ASTM draft standard F 04.25.02.02 (expulsion).

Overall, STGC 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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Cardinal Spine, LLC  
% PaxMed International, LLC  
Mr. Kevin Thomas  
Regulatory Affairs  
11234 El Camino Real, Suite 200  
San Diego, California 92130

AUG 17 2012

Re: K121176  
Trade/Device Name: STGC  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: Class II  
Product Code: MQP  
Dated: July 27, 2012  
Received: July 30, 2012

Dear Mr. 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.

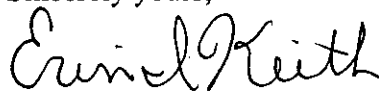
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,



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

Enclosure

**Indications for Use**

510(k) Number: K121176

Device Name: STGC

The STGC 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). The STGC is intended to be used with autograft or allograft in combination with supplemental fixation indicated for use in the thoracolumbar spine.


Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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