K100698

510(k) Summary

Cardinal Spine, LLC
STCC

MAR 14 2011

November 2, 2010

ADMINISTRATIVE INFORMATION

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Representative/Consultant:	David J. Collette, MD 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: dcollette@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	STCC
Common Name:	Intervertebral body fusion device
Classification Regulations:	21 CFR 888.3080 Class II
Product Code:	ODP
Classification Panel	Orthopedic and Rehabilitation Devices Panel
Reviewing Branch	Orthopedic Spine Devices Branch

STCC
K100698

INTENDED USE

The STCC is intended to be used as an adjunct to spinal fusion procedures at one level (C2-T1) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an anterior approach and used with autogenous bone graft and supplemental fixation, such as an anterior plating system.

DEVICE DESCRIPTION

STCC is an implantable intervertebral body fusion device manufactured from titanium alloy (Ti-6Al-4V) and is available in a variety of different sizes to suit the individual anatomic and clinical circumstances of each patient. Intended for placement via an anterior approach, the device has a trapezoidal cross section with a hollow interior designed to accommodate the placement of autologous bone graft.

PERFORMANCE DATA

Testing was performed on the STCC following protocols outlined in ASTM F2077 "Test Methods for Intervertebral Body Fusion Devices", ASTM F2267 "Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression" and in ASTM Draft Standard F-04.25.02.02 "Static Push-out Test Method for Intervertebral Body Fusion Devices" Draft #2 – August 29, 2000. The following tests were conducted in which the STCC was demonstrated to meet or exceed the biomechanical requirements of the intended use:

Static axial compression (ASTM F2077)
Dynamic axial compression (ASTM F2077)
Static torsion (ASTM F2077)
Dynamic torsion (ASTM F2077)
Static subsidence (ASTM F2267)
Static expulsion (ASTM Draft Standard F-04.25.02.02)

Conclusion: The STCC is capable of meeting the biomechanical requirements of the intended use.

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, the STCC is substantially equivalent in indications, design principles, materials and performance to the following predicate devices: the LDR Spine Cervical Interbody Fusion System (K091088) from LDR Spine USA, the Synthes Zero-P (K072981) from Synthes Spine, and the Novel® Spinal Spacer System (K081730) from Alphatec Spine, Inc.

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

MAR 14 2011

Cardinal Spine, LLC
% PaxMed International, LLC
David J. Collette, MD
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K100698
Trade/Device Name: STCC
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: March 08, 2011
Received: March 09, 2011

Dear Dr. Collette:

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" (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,

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 (if known): K100698

Device Name: STCC

Indications for Use:

The STCC is intended to be used as an adjunct to spinal fusion procedures at one level (C2-T1) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an anterior approach and used with autogenous bone graft and supplemental fixation, such as an anterior plating system.

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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