510(k) Summary

DEC 26 2006

Specialty Spine Products
SSP Vertebral Body Replacement

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Specialty Spine Products, LLC 4121 Tigris Way Riverside, CA 92503 Telephone 1 (951) 687-2808 Fax 1 (951) 734-7594
Official Contact:	Angela Carlson
Representative/Consultant:	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

DEVICE NAME

Classification Name:	Spinal intervertebral body fixation orthosis
Trade/Proprietary Name:	SSP Vertebral Body Replacement
Common Name:	Spinal vertebral body replacement device

ESTABLISHMENT REGISTRATION NUMBER

Specialty Spine Products will submit Establishment Registration to FDA prior to marketing the SSP Vertebral Body Replacement.

DEVICE CLASSIFICATION

Spinal vertebral body replacement devices are classified as Class II devices (21 CFR 888.3060). The product code for Spinal intervertebral body fixation orthosis is MQP. This device classification is reviewed by the Orthopedic Branch.

INTENDED USE

The SSP Vertebral Body Replacement is a complete or partial vertebral body replacement device intended for use in the thoracolumbar spine (T1 – L5) to provide anterior and middle column support after removal or resection of a damaged, collapsed, or unstable vertebral body due to tumor or trauma (e.g., fracture).

The SSP Vertebral Body Replacement is intended to be used with the Specialty Spine Products Pedicle Screw System or with supplemental internal fixation systems cleared for the conditions listed above, and is intended to be used with bone graft. It is designed to provide anterior column support even in the absence of fusion for a prolonged period.

DEVICE DESCRIPTION

The SSP Vertebral Body Replacement is a hollow cylinder available in either 12 mm or 14 mm diameter, with height ranging from 7 mm to 13 mm in 1 mm increments. The various sizes of these implants accommodate individual patient anatomy and pathology. Wall thickness is approximately 1.5 mm. The wall of the device features an open architecture consisting of one or two rows of circumferential holes (depending on height). The ends are notched circumferentially to form a row of "teeth" along the superior and inferior margins.

EQUIVALENCE TO MARKETED PRODUCT

Specialty Spine Products, LLC has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the SSP Vertebral Body Replacement is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices: the SynMesh Spacer System (K003275) from Synthes, the Blackstone Surgical Titanium Mesh System (K030744) from Blackstone Medical, and the Blackstone Surgical Titanium Mesh System Angled End Rings (K032700), also from Blackstone Medical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Specialty Spine Products, LLC
% Mr. Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

DEC 26 2006

Re: K061578
Trade/Device Name: SSP Vertebral Body Replacement
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: June 5, 2006
Received: June 7, 2006

Dear Mr. Larson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061578

Device Name: SSP Vertebral Body Replacement

Indications for Use:

The SSP Vertebral Body Replacement is a complete or partial vertebral body replacement device intended for use in the thoracolumbar spine (T1 – L5) to provide anterior and middle column support after removal or resection of a damaged, collapsed, or unstable vertebral body due to tumor or trauma (e.g., fracture).

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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)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061578