510(k) Summary

The 4th Column, LLC
Pillar Pedicle Screw System

JUL 26 2007

ADMINISTRATIVE INFORMATION

Sponsor Name:	The 4th Column, LLC 38 Avanzare Irvine, CA 92606 Telephone 1 (949) 551-1225 Fax 1 (866) 907 7366
Official Contact:	Kevin Armstrong
Representative/Consultant:	David J. Collette, MD or 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 or flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Pillar Pedicle Screw System
Common Name:	Pedicle screw spinal system
Classification Names:	Orthosis, Spinal Pedicle Fixation; Orthosis Spondyloisthesis Spinal Fixation
Classification Regulation:	(21 CFR 888.3070), Class II
Product Codes:	MNI, MNH

ESTABLISHMENT REGISTRATION NUMBER

The 4th Column will submit Establishment Registration information to FDA prior to marketing the Pillar Pedicle Screw System.

INTENDED USE

The Pillar Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients undergoing fusion by autogenous bone grafting having implants attached to the lumbar and sacral spine with removal of implants after the attainment of a solid fusion.

The Pillar Pedicle Screw System also is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, spinal stenosis, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis, and failed previous fusion.

DEVICE DESCRIPTION

The Pillar Pedicle Screw System is an internal fixation device for spinal surgery consisting of pedicle screws and rods that are interconnected using crosslinks and set screws. To enable close conformance to patient anatomy, pedicle screws and rods are available in various lengths, diameters, and/or contours. A series of manual surgical instruments (not a subject of this submission) intended to assist the insertion and placement of the implants are provided in an instrument tray.

EQUIVALENCE TO MARKETED PRODUCT

The 4th Column demonstrated that, for the purposes of FDA's regulation of medical devices, the Pillar Pedicle Screw System is substantially equivalent in indications and design principles to the following preamendment devices: the OPTIMA™ Spinal System (K031585) from U&i Corporation, America and the Moss Miami Spinal System (K982511, K983583, K955348) from DePuy, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The 4th Column, LLC
% Paxmed International, LLC
Mr. David Collette
Regulatory Affairs
11234 El Camino Real, Suite 200
San Diego, California 92130

JUL 26 2007

Re: K071743
Trade/Device Name: Pillar Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: June 22, 2007
Received: June 29, 2007

Dear Mr. 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.

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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K071743

Device Name: Pillar Pedicle Screw System

Indications for Use:

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Prescription Use	AND/OR	Over-The-Counter Use
X		
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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

Barbara Freeman for MAM

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K071743