510(k) Summary

JUL 24 2008

Trinity Orthopedics, LLC
Special 510(k): Device Modification

Single Planar Multi Axis (SPMA) Pedicle Screw System

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Trinity Orthopedics, LLC 8817 Production Avenue San Diego, CA 92121 Telephone: +1 (858) 689-4113 Fax: +1 (858) 689-4115
Official Contact:	James F. Marino
Representative/Consultant:	Kevin A. Thomas 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: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Single Planar Multi Axis (SPMA) Pedicle Screw System
Common Name:	Pedicle screw spinal system
Classification Name:	Orthosis, Spinal Pedicle Fixation Orthosis, Sponlyloisthesis Spinal Fixation 21 CFR 888.3070, Class II
Product Code:	MNI, MNH
Classification Panel:	Orthopedics and Rehabilitation Devices
Reviewing Branch:	Orthopedic

INTENDED USE

Trinity SPMA Pedicle Screw System 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 Single Planar Multi Axial (SPMA) Pedicle Screw System is an internal fixation device for spinal surgery consisting of rods and pedicle screw assemblies. The axle that connects the screw to the saddle allows the saddle to be adjusted in a single plane to any angle, up to 60° from the midline.

EQUIVALENCE TO MARKETED PRODUCT

The modified SPMA Pedicle Screw System has the following similarities to the unmodified predicate SPMA Pedicle Screw System:

has the same intended use,
uses the same operating principle,
incorporates the same basic design,
incorporates the same metallic materials,
is packaged and provided non-sterile in the same manner

In summary, the SPMA Pedicle Screw System, described in this submission, is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trinity Orthopedics, LLC
% PaxMed International, LLC
Mr. Kevin A. Thomas
11234 El Camino Real, Suite 200
San Diego, CA 92130

JUL 24 2008

Re: K081790
Trade/Device Name: Single Planar Multi Axis (SPMA) Pedical Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: June 24, 2008
Received: June 25, 2008

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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): K081790

Device Name: Single Planar Multi Axis (SPMA) Pedicle Screw System

Indications for Use:

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Prescription Use X (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)

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

510(k) Number K081790