7. 510(k) Summary

As Required By Section 807.92 (c)

Submitter: Custom Spine, Inc.
1140 Parsippany Blvd
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DEC 13 2007

Contact Person: Saad Attiyah
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Date Prepared: September 27, 2007

Device Class: III

Classification Name: Pedicle Screw Fixation System, Spinal Interlaminal Fixation Orthosis
Per 21 CFR §888.3070, 21 CFR §888.3050

Classification Panel: Orthopedics

Product Code: NKB,KWP,MNI,MNH

Proprietary Name: ISSYS LP Spinal Fixation System

Predicate Devices: ISSYS™ LP Spinal Fixation System (K070281)
ISSYS™ Pedicle Screw System (K043522)
Moss® Miami Spinal System (K933881, K955348, K964024, K983583, K022623)
Optima® Spinal System (K031585)

Device Description: The subject ISSYS LP Polyaxial Spinal Fixation System includes 5.5 mm diameter rods (preformed rod or straight rod configuration) in addition to the selection of the cleared 6.0 mm and 6.35 mm diameter rods. It is to be used with both the Polyaxial and Monoaxial screws

Intended Use: The ISSYS LP Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine, specifically as follows:

For pedicular use: When used as pedicle screw fixation system of the non cervical posterior spine in skeletally mature patients, these systems are indicated for one or more of the following: degenerative

spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).
In addition, this system is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (grade 3 & 4) at the L5-S1 joint having fusion with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass.

When used as non pedicular fixation system:
The ISSYS LP Spinal Fixation Systems, when used as an anterior screw fixation system and posterior sacral/iliac screw fixation system are indicated for the following:

- Degenerative disc disease of the thoracic and lumbar spine (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Spondylolisthesis
- Fracture
- Spinal deformities such as scoliosis, kyphosis, lordosis
- Tumor
- Revision of failed fusion attempts
- Pseudarthrosis
- Spinal stenosis

When used in the anterior indication the ISSYS LP Spinal Fixation Systems are indicated for use in the thoracic and lumbar spine.

Materials : Manufactured from ASTM F-136 implant grade titanium alloy.

Performance Data: Performance data per ASTM F 1717 were submitted to characterize the subject ISSYS™ LP Spinal Fixation System components address in this notification.

Summary of Technological Characteristics

Documentation is provided which demonstrates the additional 5.5 mm diameter rod of the ISSYS LP Spinal Fixation System to be substantially equivalent to the predicate devices in terms of material, design, and indications for use. Engineering analysis and testing to demonstrate compliance with FDA's Guidance For Spinal System 510(k) May 3, 2004 was completed for the ISSYS LP Spinal Fixation System, included the subject component.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

Custom Spine, Inc.
% Mr. Saad Attiyah
Manager, Regulatory Affairs & Quality Assurance
1140 Parsippany Blvd., Suite 201
Parsippany, NJ 07054

Re: K072866
Trade/Device Name: ISSYS LP Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, KWP, MNI, MNH
Dated: December 8, 2007
Received: December 13, 2007

Dear Mr. Attiyah:

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 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,

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

Enclosure

5. Indications for Use

510(k) Number (if known):K072866

Device Name: ISSYS LP Spinal Fixation System

Indications For Use:

The ISSYS LP Spinal Fixation System is intended to help provide immobilization and stabilization of the spinal segments as an adjunct to fusion of the lumbar and/or sacral spine, specifically as follows:

For pedicular use: When used as pedicle screw fixation system of the non cervical posterior spine in skeletally mature patients, these systems are indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).
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Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K072866