510(k) Summary according to 807.92(c)

JUN 11 2007

Company Contact: Aaron Markworth
Custom Spine
322 US Highway 46W
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Parsippany, NJ 07054
Phone: 973-808-0019
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Trade Name: ISSYS LP Spinal Fixation System

Classification: 21 CFR §888.3070 – Pedicle Screw Spinal System
And, §888.3050 Spinal Interlaminal Fixation Orthosis

Class: III

Product Codes: MNI, MNH, KWP, NKB

Indications For Use:

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.

The ISSYS LP Spinal Fixation System is also intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either sever spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.

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.

Device Description:

The ISSYS LP Spinal Fixation System is comprised of a variety of pedicle screws, rods, cross connectors and staples sizes that may uniquely fitted for each individual case. All implants are manufactured from medical grade titanium alloy (Ti6Al4V-ELI).

Predicate Device(s):

ISSYS LP Spinal Fixation System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used.

Performance Testing:

Pre-clinical testing performed indicated that the ISSYS LP Spinal Fixation System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Custom Spine
% Richard Jansen, Pharm. D.
Silver Pine Consulting
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K070281
Trade/Device Name: ISSYS LP Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWP, MNI, MNH
Dated: May 22, 2007
Received: May 23, 2007

JUN 11 2007

Dear Dr. Jansen:

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.

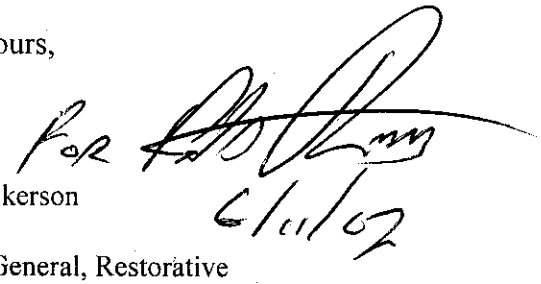
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 on 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): K070281

Indications for 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.

Prescription Use ___√___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070281