K110497

510(k) SUMMARY

February 15, 2011

SEP 2 6 2011

1. GENERAL INFORMATION

Trade Name	PASS LP Spinal System
Common Name	✓ Posterior pedicle screw system ✓ Hooks ✓ Sacral plate ✓ Iliac screw
Classification Name	✓ orthosis, spinal pedicle fixation per MNI 888.3070 ✓ orthosis, spondylolisthesis spinal fixation per MNH 888.3070 ✓ appliance, fixation, spinal interlaminal per KWP 888.3050
Class	Class II
Product Code	MNI / MNH / KWP
CFR section	888.3070 / 888.3050
Device panel	Orthopedic
Legally marketed predicate devices	PASS LP Spinal System (MEDICREA) = K062136, K080099, K082069, K082577, K083308, K083810, K100297
Reason for Special 510(k)	Addition of a component and implants delivered sterile
Submitter	MEDICREA International 14 Porte du Grand Lyon 01700 Neyron, France +33 (0)4 72 01 87 87
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 E-Mail: ortho.medix@sbcglobal.net

2. PREDICATE DEVICE DESCRIPTION

The Medicrea PASS LP Spinal System consists of pedicle screws, hooks, sacral plates, iliac screws, clamps, rods, nuts, rod plates and crosslink members. It can be used for single or multiple level fixations. Components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 or cobalt-chrome alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537.

3. DESCRIPTION OF DEVICE MODIFICATION

The purpose of this submission is to add an axial connector and to deliver the implants of the PASS LP Spinal System sterile.

4. INTENDED USE

The PASS LP Spinal System includes a pedicle system 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: fracture, dislocation, failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors.

The PASS LP Spinal System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The PASS LP also includes hooks, rods and sacral/iliac screws indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies,

spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

5. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The sterile PASS LP Spinal System is the same as the non-sterile PASS LP Spinal System. The PASS LP axial connector similar to the PASS LP derotation connector in terms of material and intended use.

Device Name / Items	PASS LP Spinal System –derotation connector	PASS LP Spinal System – axial connector
Sponsor	Medicrea	
510(k) Number	K082577	In progress
Device Classification Name	Orthosis, Spinal Fixation System	
Product Code	MNI / MNH / KWP	
Indications for Use	Same	
Material	Titanium alloy conforming to ASTM F136 or ISO 5832-3	
Size	For Ø5.5mm rod or Ø6mm rod	
Description	To connect one screw to **1 rod**	To connect one screw to **2 rods**
	Same screw attachment feature	
	Same connection to the rod	
	One plug to tight one rod	One plug on both rod
	The plug uses a torx T30	The plugs use a torx T30

6. NON-CLINICAL TEST SUMMARY

The following tests were conducted:

1. ASTM F1798 - Dynamic flexion/extension
2. ASTM F1717 – Dynamic compression bending, static compression bending, static torsion
3. ISO 11737 "Sterilization of medical devices: Estimation of the population of microorganisms on product"
4. ISO 11137-1 (2006) Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.
5. ISO 11137-2:2008, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

The results of these tests indicate that the PASS LP Spine System is equivalent to predicate devices in terms of mechanical strength and sterilization.

7. CLINICAL TEST SUMMARY

No clinical studies were performed.

8. CONCLUSIONS: NON-CLINICAL AND CLINICAL

The PASSLP Spinal System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MEDICREA International
% The OrthoMedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

SEP 26 2011

Re: K110497
Trade/Device Name: PASS LP Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: September 07, 2011
Received: September 13, 2011

Dear Mr. Webb:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

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

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K110497
Device Name: PASS LP Spinal System

PASS LP Spinal System
Indications for Use

The PASS LP Spinal System includes a pedicle system 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: fracture, dislocation, failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110497