# 510(K) SUMMARY

AUG 2 3 2011

## GENERAL INFORMATION

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|---|---|
| Trade Name | PASS Anterior Spinal System |
| Common Name | ▪ Anterolateral screw system<br>▪ Anterolateral plate |
| Classification Name | Spinal intervertebral body fixation orthosis per KWQ 888.3060 |
| Class | II |
| Product Code | KWQ |
| CFR section | 888.3060 |
| Device panel | Orthopedic |
| Legally marketed predicate devices | Colorado II Spinal System (Medtronic Sofamor Danek) = K991031<br>Expedium Anterior Spine System (Depuy Spine) = K041205<br>Moss Miami (DePuy Spine) = K964024 / K982011<br>PWB (Cross Medical) = K920116<br>Synergy VLS (Interpore Cross) = K012871<br>ISOLA (Acromed) = K980485<br>Halm Zielke Instrumentation System (Micomed Ortho) = K024125 |
| Date prepared | May 16, 2011 |
| Submitter | MEDICREA® INTERNATIONAL<br>14 Porte du Grand Lyon<br>01700 NEYRON, France |
| Contact | J.D. Webb<br>1001 Oakwood Blvd<br>Round Rock, TX 78681<br>512-388-0199<br>E-Mail: ortho.medix@sbcglobal.net |

## DEVICE DESCRIPTION

The Medicrea PASS Anterior Spinal System consists of screws, rods, plates, staples, connection and locking devices. It can be used for single or multiple level fixations, with one or two rods. This system has been developed to accommodate a left or right anterior approach. The implants are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ISO 5832-3 specifications and ASTM F136 specifications.

## INTENDED USE

The PASS Anterior Spinal System is an anterolateral screw fixation system intended to provide immobilization and stabilization of spinal segments from T4 to L5 in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic and lumbar spine:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Traumatism (ex: fracture, dislocation)
- Tumor
- Spinal deformation such as scoliosis or kyphosis
- Failed previous fusion (Pseudoarthrosis)

## SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The PASS Anterior Spinal System is similar to the Moss Miami and the Halm Zielke Instrumentation System.

| Device Name / Items | PASS Anterior Spinal System | Moss Miami | Halm Zielke Instrumentation System |
|---|---|---|---|
| **510(k) number** | / | K982011 | K024125 |
| **Sponsor** | Medicrea | Depuy Spine | Micomed |
| **Device Classification Name** | Spinal intervertebral body fixation orthosis | 888.3060/ Spinal intervertebral body fixation orthosis | 888.3060/ Spinal intervertebral body fixation orthosis |
| **Product Code** | KWQ | KWQ | KWQ |
| **Intended use** | Per KWQ | Per KWQ | Per KWQ |
| **Material** | Ti6Al4V alloy per ASTM F-136 or ISO 5832-3 | Manufactured from biocompatible Stainless Steel or Titanium | Manufactured from biocompatible Stainless Steel (316 LS) according to ASTM F1314 or Titanium (Ti 6Al 4V) according to ASTM F136 |
| **Components** | - simple screws Ø5.5, 6.5 or 7.2mm, L=25 to 50mm<br>- rods Ø5.5, L=60 to 280mm<br>- staples<br>- plates<br>- nuts<br>- dual connectors | The MOSS Miami is composed of the following major components: rod, screws and bolts. | The HALM ZIELKE Instrumentation system is composed of the followed major components: rod, screws and nuts, |

## NON-CLINICAL TEST SUMMARY

The following tests were conducted according to ASTM F1717:

1. Static testing in a load to failure mode in axial compression bending
2. Static testing in a load to failure mode in torsion
3. Cyclical axial compression bending testing

## CLINICAL TEST SUMMARY

No clinical studies were performed.

## CONCLUSIONS: NON-CLINICAL AND CLINICAL

The PASS Anterior 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
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Mr. J. D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

AUG 2 3 2011

Re: K102406
Trade/Device Name: Pass Anterior Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal invertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: July 27, 2011
Received: August 02, 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,

Erin M Keith

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

Enclosure

# INDICATIONS FOR USE

**510(k) Number (if known):** K102406

**Device Name:** PASS Anterior Spinal System

**Indications for use:**

The PASS Anterior Spinal Systems is an anterolateral screw fixation system intended to provide immobilization and stabilization of spinal segments from T4 to L5 in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic and lumbar spine:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Traumatism (ex: fracture, dislocation)
- Tumor
- Spinal deformation such as scoliosis or kyphosis
- Failed previous fusion (Pseudoarthrosis)

| 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102406