## 5. 510(K) SUMMARY

AUG 31 2010

**Submitter:** Medos International Sárl
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**Contact Person:** Daphney Germain
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**Date Prepared:** August 16, 2010

**Device Class:** Class III

**Tradename:** EXPEDIUM® Spine System

**Common Name:** Appliance, Fixation, Spinal Interlaminal;
Orthosis, Spondyloisthesis Spinal Fixation;
Orthosis, Spinal Pedicle Fixation;
Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease

**Classification Name:** Spinal interlaminar fixation orthosis
per 21 CFR §888.3050

Spinal intervertebral body fixation orthosis
per 21 CFR §888.3060

Pedicle screw spinal fixation
per 21 CFR §888.3070

**Classification Panel**: Orthopedics

**FDA Panel Number:** 87

**Product Code(s):** NKB, KWQ, KWP, MNH, MNI

**Proprietary Name:** EXPEDIUM® Spine System

**Device Description:** The EXPEDIUM Spine System is a 5.5mm and 6.35mm rod based system offered in both titanium and stainless steel. Both systems consist of the following:

- Monoaxial Screws
- Polyaxial Screws
- Uni-planar Screws

- Reduction screws
- Reduction hooks
- Hooks
- Extended Tab Implants
- Sacral Extenders
- Lateral connectors
- Washers

The proposed addition to the EXPEDIUM Spine System is a 5.5 and 6.35mm rod and plate offset system offered in both titanium and stainless steel. The EXPEDIUM Spine System will also include the following:

- Fixed Bolts
- Polyaxial Bolts
- Closed screws
- Slotted connectors
- Plates
- Nuts
- Washers
- Drop-entry connectors
- Modular cross connectors
- Transverse rod connectors
- Wires

These additional components are available in various geometries and sizes to accommodate patient anatomy. They will be provided non-sterile and sterile.

**Intended Use:**

The EXPEDIUM Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (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; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

**Materials:** Manufactured from ASTM F138 implant grade stainless steel, ASTM F136 implant grade titanium alloy, and ASTM F 562 implant grade cobalt-nickel-chromium-molybdenum alloy.

**Predicate Devices:** EXPEDIUM Spine System – K092473, K090230, K080313 K062174, and K071495
ISOLA System – K013441, K010972, and K980485
MONARCH Spine System – K024348 and K010576
VSP System – K984350
TIMX System – K981274

**Summary of Technological Differences:** The purpose of this submission is to obtain market clearance for the proposed additional components to the EXPEDIUM 5.5mm and 6.35mm Spine Systems which consist of closed screws, fixed bolts, polyaxial bolts, cross connectors, nuts, washers, wires, and plates. These proposed components have the same design characteristics, performance, intended use, and packaging as the predicate devices. The key differences between the subject and predicate devices are:

- The addition of various sizes of closed screws, fixed bolts, polyaxial bolts, cross connectors, nuts, washers, wires, and plates.
- The availability of sterile components.

**Nonclinical Test Summary:** The following mechanical tests were conducted:

- Static compression bending in accordance with ASTM F1717-04 test standard *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*. The acceptance criteria was/were met.

- Static torsion in accordance with ASTM F1717-04 test standard *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*. The acceptance criteria was/were met.

- Dynamic compression bending in accordance with ASTM F1717-04 test standard *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*. The acceptance criteria was/were met.

**Clinical Test Summary:** No clinical tests were performed.

**Conclusion:** Based on the predicate comparison and testing, the subject additions to the EXPEDIUM 5.5mm and 6.35mm Spine Systems are substantially equivalent to the predicate devices.

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

Medos International Sarl
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Ms. Daphney Germain
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AUG 31 2010

Re: K101070
Trade/Device Name: EXPEDIUM® Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: August 16, 2010
Received: August 17, 2010

Dear Ms. Germain:

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

## 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101070 AUG 31 2010

Device Name: EXPEDIUM® Spine System

Indications For Use:

The EXPEDIUM Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (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; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ ___ (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101070