# 510(k) Summary
# MIS Pedicle Screw System

## 1. Submitter Information

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JUN - 4 2010

Contact: Denise Duchene
Date Prepared: May 28, 2010

## 2. Device Information

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|---|---|
| Trade Name: | MIS Pedicle Screw System |
| Common Name: | Pedicle Screw Spinal System |
| Classification: | Class II per 21 CFR 888.3070 |
| Classification Name: | Pedicle Screw Spinal System |
| Product Code: | MNH, MNI |

## 3. Device Information

The MIS Pedicle Screw System consists of a selection of non-sterile, single use titanium alloy rod and screw components that are assembled to create a rigid spinal construct. The rod and screw components of the MIS Pedicle Screw System are attached to the non-cervical spine in order to stabilize the spine during fusion of the vertebral bodies, and are intended to be removed after spinal fusion is achieved.

## 4. Intended Use

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the MIS System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The MIS Pedicle Screw System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S1), and for whom the device is intended to be removed after solid fusion is attained.

The Spine Wave MIS Percutaneous Instruments are intended to be used with the MIS Pedicle Screw System Implants. The percutaneous instruments when used with the percutaneous cannulated screws and percutaneous rods, are intended to provide the surgeon with a percutaneous approach for posterior spinal surgery for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). As well as, for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S1), and for whom the device is intended to be removed after solid fusion is attained.

**5. Substantial equivalence**

The MIS Pedicle Screw System is substantially equivalent to the CapSure® PS Spine System (K081228 and K083353), the DePuy Spine VIPER System (K061520 and K071860) and the Medtronic CD Horizon System for use with Sextant Instrumentation (K032033 and K032265).

The MIS Pedicle System is substantially equivalent in intended use, design, materials, and construction to the predicate CapSure® PS Spine System devices. The proposed product, intended for percutaneous as well as minimally invasive placement is also equivalent to the DePuy Spine VIPER System, which is intended for percutaneous placement in the spine. As such, the MIS Screw System does not raise any new issues of safety and efficacy when compared to these legally marketed devices.

Testing was performed to support the equivalence of the proposed pedicle screw system in accordance with FDA Guidance "Guidance for Industry and FDA Staff: Spinal System 510(k)s." The following testing was performed in accordance with ASTM F1717: Static Compression Bending, Static Torsion and Dynamic Compression Bending. In addition, the technique was verified in cadaveric testing.

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

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% Ms. Denise Duchene
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Shelton, Connecticut 06484

JUN - 4 2010

Re: K100605
Trade/Device Name: MIS Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH
Dated: May 28, 2010
Received: June 01, 2010

Dear Ms. Duchene:

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,

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): _____

Device Name: MIS Pedicle Screw System

Indications for Use:

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Prescription Use __X___ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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



510(k) Number K100605