# 5. 510(K) SUMMARY

MAY 18 2012

| | |
|---|---|
| Submitter's Name: | R&D Innovation |
| Submitter's Address: | 30 Town & Country Dr, Ste 104<br>Danville, CA 94526-3930 |
| Submitter's Telephone: | Phone (925) 699-7960 or (925) 400-3010<br>Fax (925) 648-4331 or (925) 362-1045 |
| Contact Name: | Robert Rovner |
| Date Summary was Prepared: | 12/15/2011 |
| Trade or Proprietary Name: | R&D Innovation Pedicle Screw System |
| Common or Usual Name: | Pedicle Screw Spinal System |
| Classification: | Class III per 21 CFR §888.3070 |
| Product Codes: | MNI, 21 CFR 888.3070, Pedicle screw spinal system<br>MNH, 21 CFR 888.3070, Pedicle screw spinal system<br>NKB, 21 CFR 888.3070, Pedicle screw spinal system |
| Classification Panel: | Orthopedic and Rehabilitation Devices Panel |
| Predicate Devices: | Device Names:<br>ACME Spinal System, 510(K) Number: K071824<br>Moss Miami and Expedium Spinal System, 510(K) Number: K103490 & K955348 |

## DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The R&D Innovation Pedicle Screw System is a polyaxial pedicle screw system with straight or pre-contoured crosslink to provide optimal supporting structure for the spinal bodies. The pedicle screw system is a surgically implantable device which 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 thoracic, lumbar, and sacral spine.

## INDICATIONS FOR USE

When used as a pedicle screw fixation system in the non-cervical posterior spine (T1-S1) in skeletally mature patients, the R&D Innovation Pedicle Screw System is 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 the thoracic, lumbar and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) curvatures (i.e., scoliosis, kyphosis, and/or lordosis, (7) tumor, (8) failed previous fusion (i.e. pseudarthrosis).

## TECHNICAL CHARACTERISTICS

The intended use and technological features of the R&D Innovation Pedicle Screw System do not substantially differ from the legally marketed predicate devices which are the ACME Spinal System, now marketed a Spine 360 Talon Pedicle Screw System, (K071824) and DePuy Moss Miami and Expedium (K103490 & K955348). The R&D Innovation pedicle screw system and the predicate devices have similar indication for use and methods of operation.

## PERFORMANCE DATA

The R&D Innovation Pedicle Screw System has been shown to conform to the following standards, practices, and guidance:

### *STERILIZATION*

- ANSI/AAMI/ ST79:2006 and ANSI/AAMI ST79/A1:2009, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

### *BIOCOMPATIBILITY*

- ASTM F136:2008, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

### *MECHANICAL INTEGRITY*

The device also underwent static compression bending, static torsion, and dynamic compression bending testing per the following standard to ensure that performance requirements were met.

- ASTM F1717-11 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

### *CLINICAL STUDIES*

Clinical data is not necessary for this application because the standard mechanical testing results supported the substantial equivalence of the R&D Innovation Pedicle Screw System with predicate devices. The R&D Innovation Pedicle Screw System and the predicates have similar indication for use, intended us, principles of operation, and specifications in materials.

## BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use and principles of operation of the R&D Innovation Pedicle Screw System are similar to the predicate devices cited in this application. The materials used in R&D Innovation Pedicle Screw System and the predicate share the same requirements in chemical, mechanical, and metallurgical properties in accordance to ASTM F136 standard, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.* Performance testing under the guidance of ASTM F1717 standard, *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model,* demonstrates that the R&D Innovation Pedicle Screw System is functionally equivalent to the predicate devices.

## CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that R&D Innovation Pedicle Screw System is 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

MAY 18 2012

R and D Innovation, LLC
% Empirical Testing Corporation
Ms. Meredith May
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K120091
Trade/Device Name: R & D Innovation Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: December 15, 2011
Received: April 17, 2012

Dear Ms. May:

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

K120091

# 4. INDICATIONS FOR USE STATEMENT

Device Name: R&D Innovation Pedicle Screw System

When used as a pedicle screw fixation system in the non-cervical posterior spine (T1-S1) in skeletally mature patients, the R&D Innovation Pedicle Screw System is 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 the thoracic, lumbar and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) curvatures (i.e., scoliosis, kyphosis, and/or lordosis, (7) tumor, (8) failed previous fusion (i.e. pseudarthrosis).

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K120091