

**510(K) SUMMARY****A. Submitter Information**

OCT 20 2010

DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, MA 02767

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Regulatory Affairs Project Manager  
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**B. Date Prepared** 9/17/2010**C. Device Name**

*Trade/Proprietary Name:* Viper Spine System

*Common/Usual Name:* Spinal System

*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

**D. Predicate Device Name**

Trade name: DePuy Spine VIPER® Spine System (K090648)  
DePuy Spine EXPEDIUM® System (K041119, K033901, K090230, K071495)  
DePuy Spine Moss Miami® System (K011182, K953915)

**E. Device Description**

The VIPER® Systems consist of rods and cannulated screws used in a percutaneous approach and are available in various geometries and sizes. The proposed Viper® 4.35mm diameter cannulated screws maintain the identical cannulation through the center of the screw shank as the previously cleared Viper® pedicle screws. The screw shank component of the proposed screws will have the same dual lead thread form, tapered distal tip, and same flutes as the previously cleared Viper® screws and are available in polyaxial or uniplanar configurations.

#### **F. Intended Use**

The VIPER® 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 VIPER® 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.

When used in a percutaneous approach with MIS Instrumentation, the VIPER® Systems are 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.

**F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use**

The proposed modifications to the DePuy Viper® Spinal System are identical to the predicate device with one minor difference. The only change is the inclusion of polyaxial and uniplanar pedicle screws of differing diameters that were not originally cleared in the predicate 510k. The design, materials, and technology remain identical to the predicate system.

**G. Materials**

Manufactured from ASTM F 138 implant grade stainless steel and ASTM F 136 implant grade titanium alloy.

**H. Performance Data**

Performance data per ASTM F 1717 were submitted to characterize the subject VIPER System components addressed in this notification. This testing was comprised of static and fatigue testing on the proposed device. Specifically, static and dynamic compression testing as well as static torsion and cantilever beam testing were performed.

**I. Conclusion**

Both the Performance Testing and Substantial Equivalence Justification demonstrate that the device is as safe, as effective, and performs as well as the predicate device



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

OCT 20 2010

DePuy Spine, Inc.  
% Mr. Kevin G. Stevens  
Regulatory Affairs Project Manager  
325 Paramount Drive  
Raynham, Massachusetts 02767

Re: K102701  
Trade/Device Name: Viper™ Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: III  
Product Code: NKB, MNH, MNI, KWQ, KWP  
Dated: September 17, 2010  
Received: September 20, 2010

Dear Mr. Stevens:

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

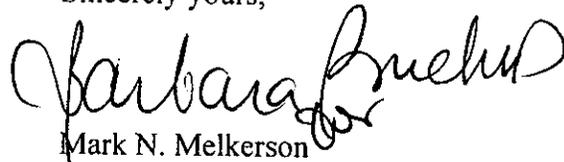
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and 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" (21 CFR 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 STATEMENT**

510(k) Number (if known): **K102701**

Device Name: Viper™ Spinal System

OCT 20 2010

Indications For Use:

The VIPER 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 VIPER 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.

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Prescription Use  X

AND/OR

Over-The-Counter Use

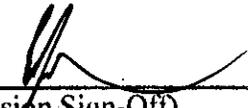
(Part 21 CFR 801 Subpart D)

(21 CFR 807 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 **K102701**