5. 510(K) SUMMARY

Submitter: DePuy Spine, Inc.
325 Paramount Drive
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NOV 15 2010

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Date Prepared: October 21, 2010

Device Class: Unclassified

Classification Name: N/A

Classification Panel: Orthopedics

FDA Panel Number: 87

Product Code(s): MRW

Proprietary Name: VIPER® F2 Facet Fixation System

Predicate Devices: DISCOVERY Facet Screw Fixation System (K012773)
PERPOS FCD-2 System (K090767)
Capture Facet Screw System (K092464)
Facet Fixation System (K061041)
Triad Facet Screw System (K020411)
Chameleon Fixation System (K071420)
VIPER System (K041801)

Device Description: The screws and washers that are the subject components of this submission are modified DISCOVERY® System screws and washers that are available in various geometries and sizes.

Intended Use: The VIPER® F2 Facet Fixation System is intended to stabilize the spine as an aid to fusion by the transfacet fixation method only:

Transfacet fixation: - The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle.

This system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: 1)

Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (ddd) as defined by back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability.

Materials: Manufactured from ASTM F 136 implant grade titanium alloy.

Comparison to Predicate Device: The substantial equivalence of the subject devices to the predicates identified above is based upon the equivalence of intended use, design (fundamental scientific technology), materials, manufacturing methods, performance, sterility, biocompatibility, safety and packaging design.

Nonclinical Test Summary: The following mechanical tests were conducted:

- Static compression bending in accordance with ASTM F1798 "*Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*".
- Dynamic compression bending in accordance with ASTM F1798 "*Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*".
- Static Three-Point bending in accordance with ASTM F1798 "*Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*".
- Dynamic Three-Point bending in accordance with ASTM F1798 "*Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*".

Clinical Test Summary: No clinical tests were performed.

Conclusion: Based on the predicate comparison and testing, the subject modified components of the DISCOVERY® System (marketed as the VIPER® F2 Facet Fixation System) 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

DePuy Spine, Inc.
% Mr. Frank Jurczak
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

NOV 15 2010

Re: K101762
Trade/Device Name: VIPER® F2 Facet Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: October 21, 2010
Received: October 22, 2010

Dear Mr. Jurczak:

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

1. INDICATIONS FOR USE STATEMENT

NOV 15 2010

510(k) Number (if known): K101762

Device Name: VIPER® F2 Facet Fixation System

Indications For Use:

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Transfacet fixation: - The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle.

This system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (ddd) as defined by back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability.

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 K101762