DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 1, 2016

Medos International SARL
% Mr. Mitch Ohiwa
Associate Director, Regulatory Affairs
DePuy Synthes Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K160904
Trade/Device Name: EXPEDIUM Spine System, VIPER and VIPER 2 Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: May 11, 2016
Received: May 13, 2016

Dear Mr. Ohiwa:

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 Parts 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160904

Device Name
EXPEDIUM Spine System, VIPER and VIPER 2 Systems

Indications for Use *(Describe)*
The EXPEDIUM Spine System and VIPER and VIPER 2 Systems are 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 and VIPER and VIPER 2 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.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER and VIPER 2 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.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EXPEDIUM Spine System and VIPER and VIPER 2 Systems metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM Spine System and VIPER and VIPER 2 Systems are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY – EXPEDIUM Spine System; VIPER and VIPER 2 Systems

A. Submitter Information

Manufacturer:	Medos International SARL Chemin-Blanc 38 2400 Le Locle, Switzerland
Submitter:	DePuy Synthes Spine 325 Paramount Drive Raynham, Massachusetts 02767
Contact Person:	Mitch Ohiwa DePuy Synthes Spine 325 Paramount Drive Raynham, Massachusetts 02767
Telephone Number:	508-828-3225
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E-mail:	mohiwa@its.jnj.com

B. Date Prepared May 11, 2016

C. Device Name

Trade/Proprietary Name:	EXPEDIUM Spine System VIPER and VIPER 2 Systems
Common/Usual Name:	Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease
Device Classification and Regulation:	Class III; 21 CFR 888.3070; Pedicle Screw Spinal System Class II; 21 CFR 888.3060; Spinal Intervertebral Body Fixation Orthosis Class II; 21 CFR 888.3050; Spinal Interlaminal Fixation Orthosis
Classification Product and Panel Code:	NKB, OSH, MNI, MNH, KWP, KWQ; Orthopedic

D. Prior Formal Correspondence

Pre-submission Q151277

E. Predicate Device Name

Primary Predicate:	EXPEDIUM Spine System and VIPER and VIPER 2 Systems (K111136)
Reference Predicates:	EXPEDIUM Spine System, VIPER and VIPER2 Systems (K131802)
	EXPEDIUM Spine System (K130877)
	VIPER System (K121020)
	EXPEDIUM and VIPER Systems (K110216)
	Moss Miami and Expedium Spine Systems (K103490)

F. Device Description

The EXPEDIUM and VIPER/VIPER 2 Spine Systems are metallic implants intended to provide immobilization and stabilization of spinal segments. They can be used for 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; or for posterior non-cervical pedicle screw fixation in pediatric patients as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM and VIPER/VIPER2 systems are intended to be used with autograft and/or allograft.

The EXPEDIUM Spine System consists of longitudinal rods, monoaxial screws, polyaxial screws, uni-planar screws, reduction screws, cable/wire screws, bolts, slotted connectors, wires, hooks, reduction hooks, transverse connectors, SFX Cross Connector System, dual rod connectors, sacral extenders, lateral connectors, and washers. The VIPER and VIPER 2 Systems consist of cannulated polyaxial screws, monoaxial screws, uni-planar screws, reduction screws, and rods used in a percutaneous approach.

G. Indications for Use

The EXPEDIUM and VIPER and VIPER 2 Systems are 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 and VIPER and VIPER 2 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.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER and VIPER 2 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.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EXPEDIUM Spine System and VIPER and VIPER 2 Systems metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM Spine System and VIPER and VIPER 2 systems are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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

The technological characteristics, performance, and intended use of the subject devices remain unchanged from the currently marketed predicate devices.

I. Materials

The materials of the subject devices remain unchanged from the currently marketed predicate devices.

The EXPEDIUM Spine System components are available in commercially pure titanium or titanium alloy conforming to ASTM F-67, ASTM F-136 or ASTM F-1472 specifications; stainless steel conforming to ASTM F-138, ASTM F-1314, or F-2229 specifications; cobalt-nickel-chromium-molybdenum alloy wire conforming to ASTM F-562 specifications; as well as longitudinal rods in cobalt-chromium-molybdenum alloy conforming to ASTM F-1537 specifications.

The VIPER and VIPER2 System components are available in titanium alloy conforming to ASTM F-136 specifications; stainless steel conforming to ASTM F-138 or ASTM F-1314 specifications; as well as longitudinal rods in cobalt-chromium-molybdenum alloy conforming to ASTM F-1537.

J. Performance Data

A review of literature, mechanical testing referencing ASTM F1717, and optical/visual analysis of suspected corrosion demonstrated that stainless steel and titanium (titanium alloys and commercially pure titanium) can be compatible even under an aggressive environment for corrosion susceptibility for a duration expected to be necessary for spinal fusion.

K. Conclusion

The titanium and stainless steel components used in the subject spinal system are substantially equivalent to the predicate devices.