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

Medos International, SARL
% Ms. Laura Bleyendaal
Senior Regulatory Affairs Specialist
DePuy Synthes
325 Paramount Drive
Raynham, Massachusetts 02767

August 31, 2017

Re: K171570
Trade/Device Name: Additional VIPER PRIME™ screws with fenestrations
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: August 4, 2017
Received: August 7, 2017

Dear Ms. Bleyendaal:

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 contact the Division of Industry and Consumer Education (DICE) 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 (DICE) 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,

Katherine D. Kavlock -S

for
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)*

K171570

Device Name
Additional VIPER PRIME™ screws with fenestrations

Indications for Use *(Describe)*

The EXPEDIUM and VIPER Spine 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 and VIPER Spine 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 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, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

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

When used in conjunction with CONFIDENCE High Viscosity Spinal Cement, the VIPER and EXPEDIUM Fenestrated Screw Systems are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The VIPER and EXPEDIUM Fenestrated Screw Systems augmented with CONFIDENCE High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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

A. Submitter Information

510(k) Sponsor:	Medos International, SARL
Contact Person:	Laura Bleyendaal DePuy Synthes 325 Paramount Drive Raynham, MA 02767
Telephone number:	(508) 828-3267
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B. Date Prepared

May 26, 2017

C. Device Name

Trade/Proprietary Name:	Additional VIPER PRIME™ screws with fenestrations
Common/Usual Name:	Thoracolumbosacral pedicle screw system
Device Classification and Regulation:	Class II per 21 CFR § 888.3070
Classification Product and Panel Code:	NKB; Orthopedic

D. Predicate Device Name

Primary Predicate Device:	VIPER PRIME™ screws with fenestrations (K170543)
Additional Predicate Device:	VIPER PRIME additions to the VIPER® System (K162912)

E. Device Description

The VIPER System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The system is composed of components offered in a range of sizes to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The system consists of bone anchors including screws, longitudinal members including rods and interconnection mechanisms including set screws. The system is compatible with transverse connectors, like the SFX cross connector from the EXPEDIUM Spine System. The system components are implanted using class I premarket notification exempt manual surgical instruments.

The purpose of this premarket notification is to add additional sizes (lengths and diameters) of VIPER PRIME screws with fenestrations. The VIPER PRIME screws with fenestrations are designed to facilitate a posterior percutaneous approach with minimally invasive surgery (MIS) instrumentation. The VIPER PRIME screws with fenestrations are intended for use with existing components of the VIPER System to generate a posterior construct to provide immobilization and stabilization of spinal segments. The VIPER PRIME screws with fenestrations are designed with a cannulation through the screw shank and lateral fenestrations and may be used in conjunction with, or without, CONFIDENCE™ High Viscosity Spinal Cement in accordance with the indications for use specified below.

F. Indications for Use

The EXPEDIUM and VIPER Spine 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 and VIPER Spine 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 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, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

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

When used in conjunction with CONFIDENCE High Viscosity Spinal Cement, the VIPER and EXPEDIUM Fenestrated Screw Systems are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The VIPER and EXPEDIUM Fenestrated Screw Systems augmented with CONFIDENCE High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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

The technological characteristics, including material, design and performance of the additional VIPER PRIME screws with fenestrations, are consistent with those of the predicate devices.

H. Materials

The VIPER PRIME screws with fenestrations are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

I. Performance Data

Dynamic compression testing (ASTM F1717), foam block testing, cement flow testing and an engineering analysis were provided in order to establish the equivalent performance of the VIPER PRIME screws with fenestrations.

J. Conclusion

The indications for use and intended use of the additional sizes of VIPER PRIME screws with fenestrations are unchanged from that of the predicate devices. The technological characteristics of the additional sizes of VIPER PRIME screws with

fenestrations in terms of design, materials and performance are consistent with those of the predicate devices. The additional sizes of VIPER PRIME screws with fenestrations are substantially equivalent to the aforementioned predicate devices.