



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

December 8, 2016

Medos International, SARL
% Ms. Laura Bleyendaal
Regulatory Affairs Associate
Depuy Synthes
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K162912

Trade/Device Name: VIPER PRIME™ additions to the VIPER® System
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: October 14, 2016
Received: October 17, 2016

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 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,
Vincent J. Devlin -S
for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162912

Device Name

VIPER PRIME™ additions to the VIPER® System

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 non-cervical 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.

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

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B. Date Prepared November 30, 2016

C. Device Name

Trade/Proprietary Name: VIPER PRIME™ additions to the VIPER® System

Common/Usual Name: Pedicle screw spinal system

Device Classification and Regulation: Class III per 21 CFR § 888.3070

Classification Product and Panel Code: NKB; Orthopedic
 KWQ; Orthopedic
 OSH; Orthopedic
 MNI; Orthopedic
 MNH; Orthopedic
 KWP; Orthopedic

D. Predicate Device Name

Primary Predicate Device: EXPEDIUM and VIPER Spine Systems (K160904)

E. Device Description

The VIPER System (including VIPER2) 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 new screws to the VIPER System. The VIPER PRIME screws are designed to facilitate a posterior percutaneous approach with minimally invasive surgery (MIS) instrumentation. The VIPER PRIME screws are intended for use with existing components of the VIPER System to generate a posterior construct to provide immobilization and stabilization of spinal segments as an adjunct to fusion.

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 non-cervical 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.

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

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

H. Materials

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

I. Performance Data

In order to characterize the VIPER PRIME screws and establish their substantial equivalence, mechanical testing was conducted in a comparative manner. The mechanical properties of the VIPER PRIME screws were evaluated through the following tests in accordance with ASTM F1717-15 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model:

- static compression bending,
- static torsion and
- dynamic compression bending.

J. Conclusion

The indications for use and intended use of the new VIPER PRIME screws are unchanged from that of the predicate devices. The technological characteristics of the VIPER PRIME screws in terms of design, materials and performance are consistent with those of the predicate devices. The VIPER PRIME screws are substantially equivalent to the aforementioned predicate devices.