October 25, 2017

Medos International SARL
% Mr. Thao Le
Regulatory Affairs Specialist II
DePuy Synthes
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K173095
Trade/Device Name: VIPER PRIME™ Screws, VIPER PRIME™ Screws with Fenestrations, EXPEDIUM® Verse Screws with Fenestrations
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: September 28, 2017
Received: September 29, 2017

Dear Mr. Le:

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,

Ronald P. Jean -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)*
K173095

Device Name
VIPER PRIME™ Screws, VIPER PRIME™ Screws with Fenestrations, EXPEDIUM® Verse 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.

510(k) Summary

A. Submitter Information

510(k) Sponsor:	Medos International SARL
Contact Person:	Thao Le DePuy Synthes 325 Paramount Drive Raynham, MA 02767
Telephone number:	508-977-6308
Fax number:	508-828-3797
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B. Date Prepared:

September 28, 2017

C. Device Name:

Trade/Proprietary Name:	VIPER PRIME™ Screws VIPER PRIME™ Screws with Fenestrations EXPEDIUM® Verse 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 KWP; Orthopedic KWQ; Orthopedic

D. Predicate Device Name

Primary Predicate Device:

Device Name	Clearance Date	510(k) Number
Additional VIPER PRIME™ Screws with Fenestrations	31AUG2017	K171570

Additional Predicate Devices:

Device Name	Clearance Date	510(k) Number
VIPER PRIME™ Additions to the VIPER® Systems	08DEC2016	K162912
VIPER PRIME™ Screws with Fenestrations	04MAY2017	K170543
VIPER® and EXPEDIUM® Fenestrated Screw Systems	20DEC2016	K160879

E. Device Description

The purpose of this premarket notification is to obtain market clearance of packaged sterile VIPER PRIME Screws, VIPER PRIME Screws with Fenestrations and EXPEDIUM Verse Screws with Fenestrations. These devices are to be provided sterile via gamma radiation.

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.

The VIPER PRIME Screws with Fenestrations and the EXPEDIUM Verse Screws with Fenestrations are intended for use with existing components of the VIPER and EXPEDIUM Verse system to generate a posterior construct to provide immobilization and stabilization of spinal segments. The VIPER PRIME Screws with Fenestration and the EXPEDIUM Verse Screws with Fenestrations are designed with a cannulation through the screw shank and 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 EXPEDIUM and 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.

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 subject devices are identical to the predicate devices, except that the subject devices will be terminally sterilized via gamma radiation. The design, materials, indications, and technology remain identical to the predicate devices.

H. Materials

The materials of the subject implants remain unchanged from that of the previously cleared implants. The VIPER PRIME Screws, VIPER PRIME Screws with Fenestrations and EXPEDIUM Verse Screws with Fenestrations are manufactured from ASTM F136 implant grade titanium alloy and ASTM F1537 Cobalt Chromium Alloy.

I. Performance Data

Performance data is not provided in this submission. Adequate description of the sterilization method has been provided.

J. Conclusion

The indications for use and intended use of the VIPER PRIME Screws, VIPER PRIME Screws with Fenestrations and EXPEDIUM Verse Screws with Fenestrations are unchanged. The technological characteristics of the VIPER PRIME Screws and VIPER

PRIME Screws with Fenestrations regarding design, materials, and performance are identical to those of the predicate devices as cleared in K162912, K170543, K171570, and K160879. These additional sterile packaged screws are substantially equivalent to the aforementioned predicate devices.