July 29, 2022

Medos International SARL
℅ Sergio M. Cordeiro
Senior Regulatory Affairs Specialist
Depuy Synthes Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K191212
Trade/Device Name: CrossOver Cross Connectors, DePuy PULSE Thoracolumbar Screw System, EXPEDIUM Fenestrated Screw System, EXPEDIUM SFX Cross Connectors, EXPEDIUM Spine System, EXPEDIUM VERSE Spine System, E-Z Link Cross Connectors, ISOLA Spine System, MONARCH Spine System, MOSS MIAMI Spine System, TiMX Low Back System, VIPER Fenestrated Screw System, VIPER PRIME System, VIPER PRIME Fenestrated Screws, VIPER SAI (Sacral-Alar-Iliac), VIPER System, VIPER 2 System, VSP Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM, NKB, JDQ, KWQ, KWP, JDN

Dear Sergio M. Cordeiro:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 24, 2019. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

September 24, 2019

Medos International SARL
% Mr. Sergio M. Cordeiro
Senior Regulatory Affairs Specialist
DePuy Synthes Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K191212
Trade/Device Name: CrossOver Cross Connectors, DePuy PULSE Thoracolumbar Screw System, EXPEDIUM Fenestrated Screw System, EXPEDIUM SFX Cross Connectors, EXPEDIUM Spine System, EXPEDIUM VERSE Spine System, E-Z Link Cross Connectors, ISOLA Spine System, MONARCH Spine System, MOSS MIAMI Spine System, TiMX Low Back System, VIPER Fenestrated Screw System, VIPER PRIME System, VIPER PRIME Fenestrated Screws, VIPER SAI (Sacral-Alar-Iliac), VIPER System, VIPER 2 System, VSP Spine System
Regulatory Class: Unclassified
Product Code: PGM, NKB, JDQ, KWQ, KWP, JDN
Dated: May 3, 2019
Received: May 6, 2019

Dear Mr. Cordeiro:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191212

Device Name
DePuy PULSE Thoracolumbar Screw System

Indications for Use *(Describe)*

The DePuy PULSE Thoracolumbar Screw System is 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 DePuy PULSE Thoracolumbar Screw System metallic components are intended for noncervical pedicle fixation and nonpedicle fixation for fusion 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.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191212

Device Name

ISOLA® Spine System, VSP® Spine System, MOSS® MIAMI Spine System, TiMX Low Back System, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH® Spine System

Indications for Use *(Describe)*

The ISOLA, VSP, MOSS MIAMI, TiMX, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH Spine Systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The ISOLA, VSP, MOSS MIAMI, TiMX, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH Spine Systems are also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The ISOLA, MOSS MIAMI, TiMX, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH Spine Systems are also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The ISOLA, VSP, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH Spine Systems when used with pedicle screws are indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

The ISOLA and MOSS MIAMI Spine Systems when used as anterior thoracic/lumbar screw fixation systems, are indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The MONARCH Spine System Dual Rod Connectors can be used to connect MONARCH Spine System Rods to rods of other DePuy Spine 4.75mm, 5.5mm, and 6.35mm diameter rod systems.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K191212

Device Name
EXPEDIUM® SFX® Cross Connectors

Indications for Use *(Describe)*

The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in posterior spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available EXPEDIUM, VIPER, VSP, ISOLA, MONARCH, MOSS MIAMI, and TiMX Spine Systems. Please refer to the labeling of the aforementioned spinal systems for each system's indications for use.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K191212

Device Name
EXPEDIUM® Spine System, EXPEDIUM VERSE® Spine System, VIPER® System, VIPER® 2 System, VIPER SAI, and VIPER PRIME

Indications for Use *(Describe)*

The EXPEDIUM Spine System, EXPEDIUM VERSE Spine System, VIPER System, VIPER 2 System, VIPER SAI, and VIPER PRIME is 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, EXPEDIUM VERSE Spine System, VIPER System, VIPER 2 System, VIPER SAI, and VIPER PRIME 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 in a posterior percutaneous approach with MIS instrumentation, the EXPEDIUM Spine System, EXPEDIUM VERSE Spine System, VIPER System, VIPER 2 System, VIPER SAI, and VIPER PRIME 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 Spine System, EXPEDIUM VERSE Spine System, VIPER System and VIPER 2 System metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM Spine System, EXPEDIUM VERSE Spine System, VIPER System, VIPER 2 System, and VIPER PRIME are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The EXPEDIUM Growing Spine System is indicated for patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The EXPEDIUM Growing Spine System may be used with any cleared traditional 4.5 and 5.5 EXPEDIUM Spine Systems. The EXPEDIUM Growing Spine System is not intended to be used with 4.0mm diameter screws.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191212

Device Name
EXPEDIUM® Fenestrated Screw System, VIPER® Fenestrated Screw System, and VIPER PRIME™ Fenestrated Screws

Indications for Use *(Describe)*

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 the 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)

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510(k) SUMMARY

A. Submitter Information

Manufacturer: Medos International SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Submitter: DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person: Sergio M. Cordeiro
325 Paramount Drive
Raynham, MA 02767
Telephone: (508) 977-2640
Fax: (508) 828-3797
Email: scordei1@its.jnj.com

B. Date Prepared **August 22, 2019**

C. Device Name

Trade/Proprietary Names:
CrossOver Cross Connectors
DePuy PULSE Thoracolumbar Screw System
EXPEDIUM® Fenestrated Screw System
EXPEDIUM® SFX® Cross Connectors
EXPEDIUM® Spine System
EXPEDIUM VERSE® Spine System
E-Z Link Cross Connectors
ISOLA® Spine System
MONARCH® Spine System
MOSS® MIAMI Spine System
TiMX Low Back System
VIPER® Fenestrated Screw System
VIPER PRIME™ System
VIPER PRIME™ Fenestrated Screws
VIPER® SAI (Sacral-Alar-Iliac)
VIPER® System
VIPER® 2 System
VSP® Spine System

Common/Usual Names: Orthosis**,** Thoracolumbar/Sacral Pedicle Screw Spinal Fixation Devices

Classification Names: PGM – Unclassified

JDQ – Class II – 21 CFR §888.3010[1]
Bone fixation cerclage

KWP – Class II – 21 CFR §888.3050
Spinal interlaminal fixation orthosis

JDN, KWQ – Class II – 21 CFR §888.3060
Spinal intervertebral body fixation orthosis

NKB – Class II – 21 CFR §888.3070
Thoracolumbosacral pedicle screw system

D. Predicate Device Names

Primary Predicate: EXPEDIUM® Spine System (K160904)

Additional Predicates: CrossOver Cross Connectors
(K012971, K021879)

DePuy PULSE Thoracolumbar Screw System
(K113396)

EXPEDIUM® Fenestrated Screw System
(K160879)

EXPEDIUM® SFX® Cross Connectors
(K111136, K160904)

EXPEDIUM VERSE® Spine System
(K142185, K160879, K173095)

E-Z Link Cross Connectors
(K001372)

ISOLA® Spine System
(K003822, K010972, K013441, K022285, K884163, K895441, K905184, K905826, K921090, K922504,

[1] The devices subject to JDQ are non-spine FDA product code classifications. However, have previously been cleared by other companies for spinal use.

K922952, K943819, K944737, K951116, K952236, K962645, K964007, K971248, K974757, K980485, K981113, K984350)

MONARCH® Spine System
(K010576, K021148, K023438, K024348, K111136)

MOSS® MIAMI Spine System
(K001105, K002607, K010742, K011182, K022623, K023804, K030383, K103490, K760649, K894184, K933881, K950695, K953915, K955348, K962628, K964024, K972568, K980447, K982011, K982320, K983583, K984378, K992168)

TiMX Low Back System
(K984348)

VIPER® Fenestrated Screw System
(K160879)

VIPER PRIME™ System
(K162912, K173095)

VIPER PRIME™ Fenestrated Screws
(K170543, K171570, K173095)

VIPER® SAI (Sacral-Alar-Iliac)
(K121020, K160904)

VIPER® System
(K101993, K102701, K110216, K111136, K111571, K160904)

VIPER® 2 System
(K111136, K160904)

VSP® Spine System
(K944736, K951116, K952236, K965102, K980485, K984350)

E. Submission Purpose

Obtain clearance for magnetic resonance compatibility labeling of the systems listed.

F. Device Descriptions

CrossOver Cross Connectors, and E-Z Link Cross Connectors

The CrossOver and E-Z Link Cross Connectors are designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. The CrossOver and E-Z Link Cross Connectors are indicated as part of the ISOLA Spinal System.

DePuy PULSE Thoracolumbar Screw System

The DePuy PULSE Thoracolumbar Screw System consists of a variety of rods, pedicle screws, connectors, setscrews and other connection components used to build a spinal construct. The DePuy PULSE Thoracolumbar Screw System is offered in titanium material in sizes ranging from 4.35mm to 12.0mm in shank diameter and 20mm to 130mm in length. Screw shanks with 7.0mm and smaller are assembled from the top of the outer head, while screws with 7.5mm and larger are assembled from the bottom using a flex ball. The implant components can be rigidly locked into a variety of configurations, with each construct being made for the individual case.

EXPEDIUM® Fenestrated Screw System, VIPER® Fenestrated Screw System, and VIPER PRIME™ Fenestrated Screws

The EXPEDIUM, VIPER and VIPER PRIME screws with fenestrations are designed with a cortical fix screw shank that is fully cannulated with lateral fenestrations at the distal end and may be used in conjunction with, or without the CONFIDENCE High Viscosity Spinal Cement. The cannulation and fenestrations allow for the injection of bone cement through the screws into the vertebral body in patients with severe osteoporosis or pathological fractures due to osteoporosis and tumor in the thoracic, lumbar and sacral spine.

EXPEDIUM® SFX® Cross Connectors

The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in constructs comprising spinal instrumentation components. It features an advanced top-loading design and unique snap-fit feature that simplify initial placement and tightening procedures which helps avoid impingement of surrounding anatomy. The EXPEDIUM SFX Cross Connector system incorporates a broad range of implant options in both and adjustable configurations for an optimal balance between dural clearance and implant profile.

EXPEDIUM VERSE® Spine System

The EXPEDIUM VERSE Spine System is designed to provide intraoperative polyaxial to monoaxial conversion. It facilitates easier rod capture and provides a powerful and precise reduction mechanism. EXPEDIUM VERSE is a reduced profile thoracolumbar

implant for use for with wide range of patient statures. EXPEDIUM VERSE is a self-contained, efficient, and intuitive instrument system that is compatible with EXPEDIUM 5.5 rods, hooks and mono screws to enhance versatility.

ISOLA® Spine System

The ISOLA Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. The ISOLA Spine System consists of connectors, open and closed iliac screws, iliac bolts, and angled closed iliac screws. These components have been designed to allow for rigid fixation of the sacral and pelvic regions of the spine.

MONARCH® Spine System

The MONARCH Spine System is both a rod-based and plate-based system designed to interface with various spinal anatomies. The plate-based system consists of pedicle screws, spine plates, transverse connectors, J-hooks, washers, nuts and set screws. The rod-based system consists of spinal rods, pedicle screws, set screws, various slotted connectors, and transverse connectors.

TiMX Low Back System

The TiMX Low Back System is a construct that consists of pedicle and sacral screws, spine plates, nuts, washers, and transverse connectors. The TiMX Low Back System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of chronic instabilities and deformities of the thoracic, lumber, and sacral spine.

MOSS® MIAMI Spine System

The MOSS MIAMI Spine System is a closure mechanism which secures the rod to the screw in one single, simple step. The unique square threads balance the forces vertically, creating a secure assembly. It consists of anatomic hooks, monoaxial screws, polyaxial screws and a dual closure mechanism.

VIPER PRIME™ System

The VIPER PRIME System is novel technique for percutaneous pedicle screw placement and posterior stabilization. This innovative technique eliminates the need for guidewires, Jamshidi needles and pedicle preparation instruments; utilizing a stylet that is fully controlled by the screwdriver. The VIPER PRIME System enables surgeons to target pedicles and insert the screw, without the need for instrument exchanges or reconfirmation of their trajectory.

VIPER® SAI (Sacral-Alar-Iliac)

The VIPER Sacral-Alar-Iliac Screw is an implant designed for sacropelvic fixation. The VIPER SAI Screw is optimized for Sacral-Alar-Iliac placement vis-à-vis a favored angle polyaxial head, smooth shank and robust drive feature. The in-line nature of this anchor allows not only stabilization but also correction of pelvic sagittal or coronal deformities.

EXPEDIUM® Spine System, VIPER® System, and VIPER® 2 System

The EXPEDIUM Spine System, VIPER System, and VIPER 2 System 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 consist 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.

VSP® Spine System

The VSP Spine System is indicated for degenerative spondylolisthesis, in skeletally mature patients, with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion. Levels of fixation are for the thoracic, lumbar and sacral spine. The VSP Spine System is also indicated for pedicle screw fixation for severe spondylolisthesis (Grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion us attained. Levels of fixation are from L3-S1.

G. Intended Use

DePuy PULSE Thoracolumbar Screw System

The DePuy PULSE Thoracolumbar Screw System is 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 DePuy PULSE Thoracolumbar Screw System metallic components are intended for noncervical pedicle fixation and nonpedicle fixation for fusion 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.

ISOLA® Spine System, VSP® Spine System, MOSS® MIAMI Spine System, TiMX Low Back System, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH® Spine System

The ISOLA, VSP, MOSS MIAMI, TiMX, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH Spine Systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The ISOLA, VSP, MOSS MIAMI, TiMX, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH Spine Systems are also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The ISOLA, MOSS MIAMI, TiMX, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH Spine Systems are also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The ISOLA, VSP, CrossOver Cross Connectors, E-Z Link Cross Connectors, and MONARCH Spine Systems when used with pedicle screws are indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

The ISOLA and MOSS MIAMI Spine Systems when used as anterior thoracic/lumbar screw fixation systems, are indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The MONARCH Spine System Dual Rod Connectors can be used to connect MONARCH Spine System Rods to rods of other DePuy Spine 4.75mm, 5.5mm, and 6.35mm diameter rod systems.

EXPEDIUM® SFX® Cross Connectors

The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in posterior spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available EXPEDIUM, VIPER, VSP, ISOLA, MONARCH, MOSS MIAMI, and TiMX Spine Systems. Please refer to the labeling of the aforementioned spinal systems for each system's indications for use.

EXPEDIUM® Spine System, EXPEDIUM VERSE® Spine System, VIPER® System, VIPER® 2 System, VIPER SAI, and VIPER PRIME

The EXPEDIUM Spine System, EXPEDIUM VERSE Spine System, VIPER System, VIPER 2 System, VIPER SAI, and VIPER PRIME is 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, EXPEDIUM VERSE Spine System, VIPER System, VIPER 2 System, VIPER SAI, and VIPER PRIME 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 in a posterior percutaneous approach with MIS instrumentation, the EXPEDIUM Spine System, EXPEDIUM VERSE Spine System, VIPER System, VIPER 2 System, VIPER SAI, and VIPER PRIME 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 Spine System, EXPEDIUM VERSE Spine System, VIPER System and VIPER 2 System metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM Spine System, EXPEDIUM VERSE Spine System, VIPER System, VIPER 2 System, and VIPER PRIME are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The EXPEDIUM Growing Spine System is indicated for patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The EXPEDIUM Growing Spine System may be used with any cleared traditional 4.5 and 5.5

EXPEDIUM Spine Systems. The EXPEDIUM Growing Spine System is not intended to be used with 4.0mm diameter screws.

EXPEDIUM® Fenestrated Screw System, VIPER® Fenestrated Screw System, and VIPER PRIME™ Fenestrated Screws

When used in conjunction with CONFIDENCE High Viscosity Spinal Cement, the EXPEDIUM Fenestrated Screw System, VIPER Fenestrated Screw System, and VIPER PRIME Fenestrated Screw System is 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 EXPEDIUM Fenestrated Screw System, VIPER Fenestrated Screw System, and VIPER PRIME Fenestrated Screw System augmented with the CONFIDENCE High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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

The subject devices maintain the design characteristics of the predicate devices. Intended use remains consistent with the predicate devices. The subject devices are provided with additional labeling language regarding magnetic resonance (MR) compatibility.

I. Materials

The subject device materials remain identical to the predicate device materials, which consist of Implant Grade 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-134, or F-2229 specifications; Cobalt-Nickel-Chromium-Molybdenum Alloy Wire conforming to ASTM F-562 specifications; and Cobalt-Chromium-Molybdenum Alloy conforming to ASTM F-1537 specifications.

J. Performance Data

Non-clinical testing was conducted in alignment with the following standards:

- ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*
- ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- ASTM F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*

- ASTM F2182 *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging*

Results demonstrated compatibility conditions of the subject devices in the MR environment.

K. Conclusion

Evaluation of subject device intended use and technological characteristics demonstrates substantial equivalence with the predicate devices. Performance data supports the addition of magnetic resonance compatibility information to subject device labeling.