April 24, 2020

Medos International Sàrl
℅ Rhoda Maddonni
Regulatory Scientist, Global Regulatory Affairs
DePuy Synthes Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K200245
Trade/Device Name: EXPEDIUM® Spine System; EXPEDIUM VERSE® Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: January 30, 2020
Received: January 31, 2020

Dear Rhoda Maddonni:

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,

Colin O'Neill, MBE
Acting Assistant Director
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)*
K200245

Device Name
EXPEDIUM® Spine System

Indications for Use *(Describe)*

The EXPEDIUM® Spine 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 EXPEDIUM® Spine 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® System is indicated as an adjunct to fusion to treat progressive spinal deformities (i.e, scoliosis, kyphosis, or lordosis) including adolescent idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the EXPEDIUM® System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. The EXPEDIUM® System is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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)*
K200245

Device Name
EXPEDIUM VERSE® Spine System

Indications for Use *(Describe)*

The EXPEDIUM VERSE® 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 EXPEDIUM VERSE® 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 in a posterior percutaneous approach with MIS instrumentation, the EXPEDIUM VERSE® 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 VERSE® System metallic implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e, scoliosis, kyphosis, or lordosis) including adolescent idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the EXPEDIUM VERSE® system is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. The EXPEDIUM VERSE® system is 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)

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510(K) SUMMARY: EXPEDIUM® Spine System and EXPEDIUM VERSE® Spine System

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: Rhoda Maddonni

Telephone: (215) 793-7022
Fax: (215) 540-4730
Email: rmaddonn@its.jnj.com

B. Date Prepared

April 24, 2020

C. Device Name

Trade/Proprietary Name: EXPEDIUM® Spine System
EXPEDIUM VERSE® Spine System

Common/Usual Name: Pedicle screw spinal system

Regulatory Class: Class II

Classification Names: NKB - 21 CFR §888.3070
Thoracolumbosacral pedicle screw system

Additional Product Codes: KWP, KWQ

Review Panel: Orthopedic

D. Predicate Devices Name

Primary Predicate: CD HORIZON® Spinal System (K162494)

Additional Predicates: Xia® 3 and Xia® 4.5 Spinal Systems (K142381)
EXPEDIUM® Spine System (K160904)
EXPEDIUM VERSE® Spine System (K142185)

E. Submission Purpose

Obtain clearance for a modified Indications for Use to broaden indications in the pediatric population for the subject devices, the EXPEDIUM® Spine System and the EXPEDIUM VERSE® Spine System.

F. Device Description

The EXPEDIUM® Spine System and the EXPEDIUM VERSE® Spine Systems consists of metallic implants intended to provide immobilization and stabilization of spinal segments. The EXPEDIUM® Spine System and the EXPEDIUM VERSE® Spine Systems also 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.

G. Indications for Use

The EXPEDIUM® Spine System

The EXPEDIUM® Spine 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 EXPEDIUM® Spine 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® System is indicated as an adjunct to fusion to treat progressive spinal deformities (i.e, scoliosis, kyphosis, or lordosis) including adolescent idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the EXPEDIUM® System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. The EXPEDIUM® System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The EXPEDIUM VERSE® Spine System

The EXPEDIUM VERSE® 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 EXPEDIUM VERSE® 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 in a posterior percutaneous approach with MIS instrumentation, the EXPEDIUM VERSE® 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 VERSE® System metallic implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e, scoliosis, kyphosis, or lordosis) including adolescent idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the EXPEDIUM VERSE® system is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. The EXPEDIUM VERSE® system is 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 intended use, technological characteristics, and performance of the EXPEDIUM® Spine System and the EXPEDIUM VERSE® Spine System are consistent with those of the predicate devices for the expanded pediatric indication as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including adolescent idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the EXPEDIUM® Spine System and the EXPEDIUM VERSE® Spine System are intended to treat pediatric patients diagnosed with: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion.

I. Materials

The EXPEDIUM® Spine System and the EXPEDIUM VERSE® Spine System components are available in commercially pure titanium or titanium alloy conforming to ASTM F67, ASTM F136 or ASTM F1472 specifications; stainless steel conforming to ASTM F138, ASTM F1314, or F2229 specifications; cobalt-nickel-chromium-

molybdenum alloy wire conforming to ASTM F562 specifications; as well as longitudinal rods in cobalt-chromium-molybdenum alloy conforming to ASTM F1537 specifications.

J. Performance Data

Evaluation of the subject devices' intended use, technological characteristics, device performance and system components were performed. Additional performance data is not provided since this submission seeks a broadening of pediatric indications only.

K. Conclusion

The expanded pediatric indications of the EXPEDIUM® Spine System and the EXPEDIUM VERSE® Spine System (subject devices) are identical to the cleared pediatric indications of the predicates CD HORIZON® Spinal System and Xia® 3 and Xia® 4.5 Spinal Systems. The evaluation of the subject devices' intended use, technological characteristics, and system components demonstrates substantial equivalence with the predicate devices.