October 13, 2022

Medos-International, SARL
% Denielle Smith
Regulatory Affairs Specialist
DePuy Spine
325 Paramount Dr.
Raynham, Massachusetts 02767

Re: K222473
Trade/Device Name: EXPEDIUM® Spine System, EXPEDIUM VERSE® Spine System: ALTALYNE™ Ultra Rods
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: August 16, 2022
Received: August 16, 2022

Dear Ms. Smith:

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, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222473

Device Name
EXPEDIUM® Spine System, EXPEDIUM VERSE® Spine System: ALTALYNE™ Ultra Rods

Indications for Use *(Describe)*

EXPEDIUM Spinal 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, pseudarthrosis; and failed previous fusion in skeletally mature patients.

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

EXPEDIUM VERSE Spinal System

The EXPEDIUM VERSE 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 VERSE 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, pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EXPEDIUM VERSE Spine 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 Spine 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 Spine 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.

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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
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Contact Person:
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Email: dsmith76@its.jnj.com

B. Date Prepared

October 11, 2022

C. Device Name

Trade/Proprietary Name: EXPEDIUM® Spine System, EXPEDIUM VERSE® Spine System: ALTALYNE™ Ultra Rods

Common/Usual Name: Thoracolumbosacral pedicle screw system

Regulatory Class: II

Review Panel: Orthopedic

Product Codes:
NKB – 21 CFR §888.3070
Thoracolumbosacral Pedicle Screw System

KWP – 21 CFR §888.3050
Appliance, Fixation, Spinal Interlaminal

D. Predicate Device Names

Primary Predicate: EXPEDIUM® Spine System and EXPEDIUM VERSE® Spine System (K200245)

E. Device Description

The EXPEDIUM Spine System and the EXPEDIUM VERSE Spine System consists of metallic implants intended to provide immobilization and stabilization of spinal segments. The EXPEDIUM Spine System and the EXPEDIUM VERSE Spine System also consists of longitudinal rods, monoaxial screws, polyaxial screws, uniplanar screws, reduction screws, cable/wire screws, set screws, bolts, slotted connectors, wires, hooks, reduction hooks, transverse connectors, SFX Cross Connector System, dual rod connectors, sacral extenders, lateral connectors, and washers.

F. Intended Use / Indications for Use

The indications for use of the subject devices are identical to the current EXPEDIUM and EXPEDIUM VERSE indications:

EXPEDIUM Spinal 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, pseudarthrosis; and failed previous fusion in skeletally mature patients.

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

EXPEDIUM VERSE Spinal System

The EXPEDIUM VERSE 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 VERSE 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, pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EXPEDIUM VERSE Spine 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 Spine 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 Spine System is 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 intended use, technological characteristics, and performance of the subject devices are consistent with those of the predicate devices.

H. Materials

The EXPEDIUM Spine System and the EXPEDIUM VERSE Spine System components are manufactured from 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-chromium-molybdenum alloy conforming to ASTM F1537 specifications; and cobalt-nickel-chromium molybdenum conforming to ASTM F562 specifications.

I. Performance Data

The following performance data is provided in support of substantial equivalence determination:

Mechanical testing (ASTM F1717, F1798)

Corrosion and wear testing (ASTM F3044, ASTM G102, ASTM F2129, ASTM F1877)

Magnetic Resonance testing (ASTM F2052, ASTM F2119, ASTM F2182)

Biocompatibility testing (ISO 10993-1)

J. Conclusion

Evaluation of the subject device intended use, technological characteristics, and performance data demonstrates substantial equivalence with the predicate devices.