March 8, 2022

Medos International SARL
Megan Smith
Regulatory Affairs Specialist
Depuy Synthes Spine
325 Paramount Dr
Raynham, Massachusetts 02767

Re: K220374
Trade/Device Name: EXPEDIUM VERSE® Fenestrated Screw System (Sterile Fenestrated Screws)
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: February 7, 2022
Received: February 9, 2022

Dear Megan 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)*
K220374

Device Name
EXPEDIUM VERSE® Fenestrated Screw System (Sterile Fenestrated Screws)

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 adolescent idiopathic scoliosis. The EXPEDIUM Verse system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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.

When used in conjunction with CONFIDENCE High Viscosity Spinal Cement, the EXPEDIUM VERSE 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 EXPEDIUM Fenestrated Screw System augmented with the CONFIDENCE High Viscosity Spinal Cement is 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.

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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: Megan Smith
Telephone: 978-538-8797
Email: msmith94@its.jnj.com

B. Date Prepared February 7, 2022

C. Device Name

Trade/Proprietary Name: **EXPEDIUM VERSE® Fenestrated Screw System (Sterile Fenestrated Screws)**

Common/Usual Name: Thoracolumbosacral Pedicle Screw System

Regulatory Class: *21 CRF 888.3070, 888.3060, 888.3050*

Product Codes: *NKB, KWQ, KWP*

D. Predicate Device Names

Predicate: **EXPEDIUM® Spine System; EXPEDIUM VERSE® Spine System – K200245**

Device Description Summary

The EXPEDIUM fenestrated screws are polyaxial pedicle screws designed with a cannulation that runs the length of the screw shank and lateral fenestrations. The fenestrated screws are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. The EXPEDIUM VERSE® fenestrated screws are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 and cobalt chromium alloy (Co-28Cr-6Mo) conforming to ASTM F1537. The fenestrated screws are intended for use with components of the EXPEDIUM System such as rods and set screws to create an implant system to meet the patient's physiological and anatomical requirements. The EXPEDIUM VERSE® fenestrated screws are intended for use with components of the EXPEDIUM Spine System, including VERSE, to create an implant system to meet the patient's physiological and anatomical requirements.

The fenestrated screws may be used in conjunction with CONFIDENCE High Viscosity Spinal Cement a self-curing polymethylmethacrylate (PMMA) radiopaque bone cement. The CONFIDENCE Spinal Cement System® kits include the cement and accessories necessary to mix, prepare and deliver the cement. The fenestrated screw cannula connects the CONFIDENCE spinal cement delivery system to the fenestrated screw. An alignment guide facilitates orientation of the fenestrated screw to accept the fenestrated screw cannula for cement delivery. Please refer to the surgical technique manual.

Indications for Use

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.

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involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The EXPEDIUM Fenestrated Screw System augmented with the CONFIDENCE High Viscosity Spinal Cement is for use at spinal levels where the structural integrity of the spine is not severely compromised.

Indications for Use Comparison

The indications for use are comparable between the subject and predicate devices

Technological Comparison

The only change is a labeling change to allow for reprocessing of the sterile fenestrated screws once they are removed from sterile packaging and rendered non-sterile but prior to use. The screws remain single use implants identical to the predicate. There is no change to the design of the screws including the schematics, material, principle of operation, packaging, biocompatibility, or MR compatibility from the predicate device. When in sterile packaging, the subject devices are identical to the sterile versions of the predicate. Once removed from sterile packaging but prior to use, the subject devices are identical to the non-sterile versions of the predicate and follow the same cleaning and reprocessing instructions contained in the instructions for use as the predicate non-sterile devices.

Non-Clinical and/or Clinical Tests Summary

No additional testing was conducted to support this submission.

Conclusion

Based on engineering analyses, the subject device with the proposed labeling update regarding “opened-but-unused” language is substantially equivalent to the predicate device. The indications for use, technological characteristics, and performance are comparable. Therefore, the proposed modifications raise no new questions of safety or effectiveness.