September 22, 2023

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

Re: K231479
Trade/Device Name: TriALTIS Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, PML
Dated: May 22, 2023
Received: August 24, 2023

Dear Denielle 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 -S

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.

Submission Number *(if known)*

K231479

Device Name

TriALTIS Spine System

Indications for Use *(Describe)*

The TriALTIS™ 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 TriALTIS™ Spine System is intended for pedicle fixation of the thoracic, lumbar, and sacral spine (T1-S2) 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 pedicle screw fixation of the thoracic, lumbar, and sacral spine (T1-S2) in pediatric patients, the TriALTIS™ Spine System metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The TriALTIS™ Spine System is intended to be used with autograft and/or allograft. Pediatric screw fixation is limited to a posterior approach.

When used for posterior pedicle screw fixation of the thoracic, lumbar, and sacral spine (T1-S2) in pediatric patients, the TriALTIS™ Spine 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 TriALTIS™ 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 TriALTIS™ Spine System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

When the TriALTIS™ Spine System fenestrated screws are used in conjunction with CONFIDENCE™ High Viscosity Spinal Cement, the TriALTIS™ Spine System is intended to stabilize 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 TriALTIS™ fenestrated screws 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.

510(k) #: K231479

510(k) Summary

Prepared on: 2023-09-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medos International SARL
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Correspondent Contact	Dr. Megan Smith
Correspondent Contact Email	msmith94@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TriALTIS Spine System
Common Name	Thoracolumbosacral pedicle screw system
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3070
Product Code	NKB, PML

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200245	EXPEDIUM Spine System and EXPEDIUM VERSE Spine Syste	NKB
K220374	EXPEDIUM VERSE Spine System fenestrated screws	NKB
K160879	VIPER and EXPEDIUM Spine System fenestrated screws	PML
K160904	Expedium, Viper, Verse Spine Systems	NKB
K170543	Viper PRIME Spine System	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The TriALTIS Spine System is a posterior spinal fixation system intended to provide immobilization and stabilization of spinal segments

as an adjunct to fusion of the thoracic lumbar and sacral spine (T1-S2). The system is composed of multiple components to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The system consists of bone anchors (such as screws) for connection by longitudinal components (such as rods) via an interconnection mechanism (e.g., set screws) to link the longitudinal components for additional stability. The TriALTIS System implant components are comprised of Titanium alloy conforming to ASTM F136, and Cobalt-Chromium-Molybdenum alloy conforming to ASTM F1537.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The TriALTIS™ 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 TriALTIS™ Spine System is intended for pedicle fixation of the thoracic, lumbar, and sacral spine (T1-S2) 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.

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When the TriALTIS™ Spine System fenestrated screws are used in conjunction with CONFIDENCE™ High Viscosity Spinal Cement, the TriALTIS™ Spine System is intended to stabilize 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 TriALTIS™ fenestrated screws 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 21 CFR 807.92(a)(5)

Indications of the subject device are similar to that of EXPEDIUM and EXPEDIUM VERSE with CONFIDENCE. The indications of the subject device clarifies "noncervical" as "thoracic, lumbar and sacral spine (T1-S2)."

Technological Comparison 21 CFR 807.92(a)(6)

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

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The TriALTIS Spine System was evaluated against the predicate system, EXPEDIUM, using ASTM F1717 standard setup for Static and Dynamic Construct Compression Bending and Static Construct Torsion Testing.

Additionally, use of TriALTIS fenestrated screws with CONFIDENCE cement was evaluated against the predicate EXPEDIUM VERSE Spine System fenestrated screws.

Clinical testing is not applicable.

Evaluation of the subject device performance data as compared to the predicate systems has found that the TriALTIS Spine system has a substantially equivalent safety and effectiveness profile compared to the predicate system identified above.