October 21, 2025

Medos International SARL
% Sravya Lahari Sripada
Sr. Regulatory Affairs Specialist
Pioneer Surgical Technologies, Inc.
375 River Park Circle
Marquette, Michigan 49855

Re: K253249
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, KWP, KWQ, PML
Dated: September 24, 2025
Received: September 29, 2025

Dear Sravya Lahari Sripada:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253249

Please provide the device trade name(s).

TriALTIS™ Spine System

Please provide your Indications for Use below.

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) and nonpedicle fixation 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253249

510(k) Summary

Prepared on: 2025-09-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medos International SARL
Applicant Address	Chemin-Blanc 38 2400 Le Locle Switzerland
Applicant Contact Telephone	781-366-7496
Applicant Contact	Mr. Andrew Willwerth
Applicant Contact Email	Awillwe1@its.jnj.com
Correspondent Name	Pioneer Surgical Technologies, Inc.
Correspondent Address	375 River Park Circle Marquette MI 49855 United States
Correspondent Contact Telephone	240-460-9543
Correspondent Contact	Mrs. Sravya Lahari Sripada
Correspondent Contact Email	ssripada@exalta.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(s)	NKB, KWP, KWQ, PML

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231479	TriALTIS™ Spine System	NKB
K200245	EXPEDIUM® Spine System; EXPEDIUM VERSE® Spine System	NKB
K233684	TriALTIS™ 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 and connectors) to link the longitudinal components for additional stability. The TriALTIS™ Spine System implants are comprised of Titanium

alloy conforming to ASTM F136 and Nitinol conforming to ASTM F2063. Implants of the TriALTIS™ Spine System may be provided either sterile or non-sterile and this will be clearly identified on the product labels.

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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Indications for Use Comparison

21 CFR 807.92(a)(5)

The TriALTIS™ Spine System Indications for Use included in this Special 510(k) are the same as the previously cleared TriALTIS™ Spine System Indications for Use.

Technological Comparison

21 CFR 807.92(a)(6)

Evaluation of the subject device intended use, the 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)

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 systems identified above.