November 21, 2023

OSTEOMED Indústria e Comércio de Implantes LTDA
Fernando Neto
Official Correspondent
Washington Luis Route, 172 km - Anhanguera's Garden
Rio Claro, São Paulo 13500-970
Brazil

Re: K231443
Trade/Device Name: Mini-OSTEO Pedicle Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: November 1, 2023
Received: November 1, 2023

Dear Fernando Neto:

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.

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

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)*
K231443

Device Name
Mini-OSTEO Pedicle Fixation System

Indications for Use *(Describe)*
The Mini-OSTEO Pedicle Fixation System is intended for posterior, non-cervical pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine: degenerative disc disease (DDD) 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/or failed previous fusion.

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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OSTEOMED Industria e
Comércio de Implantes LTDA
Traditional 510(k)

GENERAL INFORMATION

Date Prepared:	November 09th, 2022
Trade name:	Mini-OSTEO Pedicle Fixation System
Common name:	Pedicle Screw Spinal System
Classification:	Thoracolumbosacral Pedicle Screw System, Class II
Product Codes:	NKB, KWP
Device Panel:	Orthopedic
CFR section:	21 CFR 888.3070 21 CFR 888.3050
Predicate Devices:	K162494 - CD Horizon® Spinal System, Mecatronic, Inc. K122226 - Revere® Stabilization System, Globus Medical, Inc. K190636 - Reline 4.5-5.0 System, NuVasive
Submitter:	Fernando Argenton Neto (Responsible Engineer) regulatorios@osteomedimplantes.com
Contact:	Davis Machado Larrubia (Project's Manager) davis.projetos@osteomedimplantes.com
Applicant:	OSTEOMED Industria e Comércio de Implantes LTDA. Washington Luis Route, 172 km - Anhanguera's Garden Zip Code:13500-970 - + 55 19 3522-3064 - Rio Claro - São Paulo - Brazil

DEVICE DESCRIPTION

The Mini-OSTEO Pedicle Fixation System consists of the following non-sterile, single-use components: monoaxial screws, polyaxial screws, rods, pedicle bars, laminar and transverse hooks, connectors, and a pedicle locking component for connectors. The connectors are provided in a variety of sizes and shapes to accommodate variations in anatomy and spacing/positioning of existing screw and rod hardware.

Materials
- Unalloyed Titanium conforming to ASTM F67
- Ti6Al4V Alloy conforming to ASTM F136

SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The Mini-OSTEO Pedicle Fixation System are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K222229	Advanced LumFix Spinal Fixation System	CG Bio Co., Ltd.	NKB	Primary
K223096	Dark Star Deformity Pedicle Screw System	Republic Spine, LLC	NKB, KWP	Additional

INDICATIONS FOR USE

The Mini-OSTEO Pedicle Fixation System is intended for posterior, non-cervical pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine: degenerative disc disease (DDD) 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/or failed previous fusion.

NON-CLINICAL TEST SUMMARY

The following tests were conducted:

- Evaluation of the Test Methods For Spinal Implant as per ASTM F1717
- Torsion, Driving Torque, Insertion and Remotion Torques, and Axial Pullout as per ASTM F543
- Evaluation of the Interconnection Mechanisms And Subassemblies Used In Spinal Arthrodesis Implants as per ASTM F 1798

The results of this testing indicate that the Mini-OSTEO Pedicle Fixation System are equivalent to predicate devices.

CLINICAL TEST SUMMARY

No clinical studies were performed

NON-CLINICAL CONCLUSIONS

OSTEOMED Implantes considers the the Mini-OSTEO Pedicle Fixation System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.