January 10, 2018

Silony Medical GmbH
% Ms. Indraj Bamrah
Senior Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K171421
Trade/Device Name: VERTICALE® Posterior Spinal Fixation System/VERTICALE® System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: December 6, 2017
Received: December 8, 2017

Dear Ms. Bamrah:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171421

Device Name
VERTICALE® Posterior Spinal Fixation System / VERTICALE® System

Indications for Use *(Describe)*
The VERTICALE® 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 VERTICALE® System is intended for non-cervical 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 VERTICALE® MIS System is intended for non-cervical 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 VERTICALE® and VERTICALE® MIS metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The subject device 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

VERTICALE® POSTERIOR SPINAL FIXATION SYSTEM K171421

1. Submission Sponsor

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Contact: Indraj Bamrah
Title: Senior Regulatory Consultant

3. Date Prepared

December 06, 2017

4. Device Identification

Trade/Proprietary Name: VERTICALE® Posterior Spinal Fixation System / VERTICALE® System

Common/Usual Name:	Pedicle Screw Spinal System
Classification Name:	Pedicle Screw Spinal System
Regulation Number:	21 CFR 888.3070 Thoracolumbosacral Pedicle Screw System
Product Code:	NKB, KWP
Device Class:	Class II
Classification Panel:	Orthopedic

5. Legally Marketed Predicate Device(s)

Primary Predicate

K131802, Expedium Spine System,VIPER and VIPER 2 Systems Medos International Sárl.

Additional Predicate

K092287, NuVasive SpheRx II (Armada) – Pedicle Screw System, NuVasive Inc.

6. Indication for Use Statement

The VERTICALE® 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 VERTICALE® System is intended for non-cervical 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 VERTICALE® MIS System is intended for non-cervical 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 VERTICALE® and VERTICALE® MIS metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The subject device is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

7. Device Description

The VERTICALE® System is a posterior fixation system for stabilizing the thoracic, lumbar and sacral spine. The VERTICALE® System is a modular, versatile fixation system consisting of pedicle screws, iliac screws, revision screws, hooks and rods for the fusion of treated spinal segments.

The pedicle screws are available in a range of sizes, and in solid, cannulated or cannulated and fenestrated designs, which when used in combination with the rods, can be used for a range of indications. The pedicle screws and hooks are manufactured from titanium alloy and the rods, from titanium alloy or cobalt chrome alloy.

The VERTICALE® System comprises modular ergonomically designed, bi-functional two-in-one (2 in 1) instruments with modular handle options. The VERTICALE® System also offers a set of

minimal invasive instrumentation (MIS) to facilitate minimally invasive implantation of the components.

The VERTICALE® System is color coded by diameter for ease of identification.

The VERTICALE® implants are manufactured from Ti6Al4V ELI conforming to ASTM F136 and CoCrMo conforming to ASTM F1537. The VERTICALE® System specific instruments are manufactured from materials conforming to ISO 16061 and ASTM F899.

The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

8. Substantial Equivalence Discussion

The VERTICALE® System has been shown to be substantially equivalent to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of VERTICALE® System and in showing substantial equivalence to the predicate devices, Silony Medical GmbH completed a number of non-clinical performance tests. The VERTICALE® System meets all the requirements for overall design, sterilization, biocompatibility, and performance testing results confirming that the design output meets the design inputs and specifications for the device.

The VERTICALE® System passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Mechanical testing – Tested in accordance with ASTM F1717-15 for static compression bending, static tension bending, static torsion and fatigue with acceptable results.
- Mechanical testing – Tested in accordance with ASTM F1798-13 for static axial slipping, polyaxial slipping, head splay and fatigue with acceptable results.
- Biocompatibility – Biological evaluation was performed according to 10993-1 on known materials supporting that no toxic substances or materials are used; materials used for the subject device are materials all used in marketed implant devices.
- Validation activities have been successfully conducted for cleaning and sterilization, packaging, shelf life and transport.

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of

the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device; or the device has the same intended use and different technological characteristics, but it can be demonstrated that the device is substantially equivalent to the predicate device and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate devices.

The VERTICALE® System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.