April 7, 2020

Silony Medical GmbH
Melanie Lubjuhn
Team Leader Regulatory Affairs
Leinfelder StraBe 60
Leinfelden-Echterdingen, 70771 De

Re: K192013
Trade/Device Name: VERTICALE® Cervical System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: March 11, 2020
Received: March 13, 2020

Dear Melanie Lubjuhn:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192013

Device Name
VERTICALE® Cervical System

Indications for Use *(Describe)*
The VERTICALE Cervical System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction (occiput-C2), the cervical spine (C1 to C7) and the thoracic spine (T1-T3):
- traumatic spinal fractures and /or traumatic dislocations
- instability or deformity
- failed previous fusions (e.g. pseudoarthrosis)
- tumors involving the cervical/thoracic spine
- degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and
- degenerative disease of the facets with instability

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® Cervical System

1. Submission Sponsor

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3. Date Prepared

26th July 2019

4. Device Identification

Trade/Proprietary Name:	VERTICALE® Cervical System
Common/Usual Name:	Posterior Cervical Screw System
Regulation Number:	888.3075
Product Code:	NKG, KWP
Device Class:	II
Classification Panel:	Orthopedic

5. Legally Marketed Primary Predicate Device

Mountaineer OCT Spinal System; DePuy Spine, Inc.; K151885

6. Device Description

The VERTICALE Cervical System is a posterior double rod fixation system for immobilization and stabilization of the spinal segments of the craniocervical junction (occiput-C2), cervical spine (C1-C7), and thoracic spine (T1-T3).

The system may only be used in the field of human medicine and consists of polyaxial screws, favored angle polyaxial (FA) screws, rods, occiput plates, connectors and the related instrumentation.

The VERTICALE Cervical System will be used in patients with occiput cervical and upper cervical spine instabilities.

The implants of the VERTICALE Cervical System are manufactured from titanium alloy conforming to ASTM F136 / ISO 5832-3. They are delivered in a sterile condition and can be used without any further preparations. The implants are packaged in accordance with EN ISO 11607 Part 1+2 and sterilized with gamma irradiation at a minimum dose of 25 kGy.

Implants delivered by the manufacturer in a sterile condition may not be sterilized. They are intended for single use.

7. Indication for Use Statement

The VERTICALE Cervical System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction (occiput-C2), the cervical spine (C1 to C7) and the thoracic spine (T1-T3):

- traumatic spinal fractures and /or traumatic dislocations
- instability or deformity
- failed previous fusions (e.g. pseudoarthrosis)
- tumors involving the cervical/thoracic spine
- degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and
- degenerative disease of the facets with instability

8. Substantial Equivalence Discussion

The VERTICALE Cervical system has shown to be substantial equivalent to the predicate device mentioned in chapter 5 of this section with respect to indications for use, principles of operations, technological characteristics, materials and performance testing.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the VERTICALE Cervical System and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, Silony Medical completed a number of non-clinical performance tests. The VERTICALE Cervical System meets all the requirements for overall design, sterilization, biocompatibility, and performance testing results confirming that the design output meets the design inputs specifications for the device.

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

- Mechanical performance according to:
    - ASTM F1717-18: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model (static and dynamic compression bending and static and dynamic torsion)
    - ASTM F2706-18: Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model (static and dynamic compression bending and static and dynamic torsion)
    - ASTM F1798-13: Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants (static axial grip and static and dynamic flexion-extension)
- Biocompatibility according ISO 10993-1
- Cleaning and Sterilization testing according ISO 11137
- Shelf Life testing for 10 years
- Storage and Transport testing

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

11. Statement of Substantial Equivalence

The VERTICALE Cervical System is determined to be substantially equivalent to the referenced predicate device.