Silony Medical GmbH
℅ Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th St, NW
Washington, District of Columbia 20001

July 6, 2023

Re: K223806
Trade/Device Name: VERTICALE® Triangular Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 13, 2023
Received: June 13, 2023

Dear Mr. Eggleton:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.07.06 10:14:39 -04'00'

for

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)*
K223806

Device Name
VERTICALE® Triangular Fixation System

Indications for Use *(Describe)*
The VERTICALE® Triangular Fixation System, when used in combination with the VERTICALE® Posterior Spinal Fixation System, is intended for immobilization and stabilization of the 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® Triangular Fixation System is intended to treat the following conditions: trauma (i.e., fracture or dislocation); tumor, pseudoarthrosis; and failed previous fusion.

The VERTICALE® Triangular Fixation System is intended for iliac fixation and must be attached to the VERTICALE® Posterior Spinal Fixation System to treat the conditions listed above.

Refer to the labeling for the VERTICALE® Posterior Spinal Fixation System for limitations and instructions for use.

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

Contact: Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
MCRA, LLC
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Washington, DC 20001
Phone: 202.552.5800
Email: jeggleton@mcra.com

Date Prepared: June 13, 2023

Device Trade Name: VERTICALE® Triangular Fixation System

Manufacturer: Silony Medical GmbH
Leinfelder Straße 60
70771 Leinfelden-Echterdingen
Germany

Common Name: Thoracolumbosacral pedicle screw system

Classification: 21 CFR §888.3070, Thoracolumbosacral pedicle screw system

Class: II

Product Code: NKB

Indications For Use:
The VERTICALE® Triangular Fixation System, when used in combination with the VERTICALE® Posterior Spinal Fixation System, is intended for immobilization and stabilization of the 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® Triangular Fixation System is intended to treat the following conditions: trauma (i.e., fracture or dislocation); tumor, pseudoarthrosis; and failed previous fusion.

The VERTICALE® Triangular Fixation System is intended for iliac fixation and must be attached to the VERTICALE® Posterior Spinal Fixation System to treat the conditions listed above.

Refer to the labeling for the VERTICALE® Posterior Spinal Fixation System for limitations and instructions for use.

Device Description:
The VERTICALE® Triangular Fixation System consists of iliac screws with a UHMWPE lined slot, a polyaxial head as well as related instruments. The VERTICALE® Triangular Fixation System is intended to be used with VERTICALE® Posterior Spinal Fixation System (K171421).

The implants of the VERTICALE Triangular Fixation System are manufactured from titanium alloy conforming to ASTM F136 / ISO 5832-3 and Ultra-High-Molecular-Weight Polyethylene according to ASTM F648 / ISO 5834-1 and -2.

Predicate Device:
Primary Predicate: VERTICALE® Posterior Spinal Fixation System, Silony Medical, K171421

Reference Device: Attune Knee System, DePuy Synthes, K101433

Substantial Equivalence:
Non-clinical testing and engineering rationales were provided as justification for substantial equivalence of the VERTICALE® Triangular Fixation System to the predicate devices.

Performance Testing Summary
The performance testing included tests conducted according to ASTM F543 (insertion testing, torsional properties) and ASTM F1717 (static compression bending, static torsion, static tension bending, dynamic compression bending) used to demonstrate the substantially equivalent mechanical performance of the subject device to legally marketed predicates.

Conclusion:
The subject device is substantially equivalent to the predicate devices with respect to indications for use, design, function, materials, and performance. Additionally, the provided performance data related to the subject device supports this traditional 510(k), for the VERTICALE® Triangular Fixation System.