February 19, 2026

Silony Medical GmbH
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K254148
Trade/Device Name: VERTICALE GPS Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 4, 2025
Received: December 22, 2025

Dear Nathan Wright:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254148

Device Name
VERTICALE GPS Instruments

Indications for Use *(Describe)*
The VERTICALE® GPS Instruments are indicated to be used during the preparation and placement of VERTICALE® pedicle screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures for skeletally mature patients, where reference to a rigid anatomical structure such as vertebra can be identified. These instruments are designed for use with the Globus ExcelsiusGPS™ system, which is indicated for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

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.

K254148 - 510(K) SUMMARY

Submitter's Name: Submitter's Address: Submitter's Telephone:	Silony Medical GmbH Leinfelder Straße 60 Leinfelden-Echterdingen Baden-Württemberg, Germany 70771 +49 (0) 711-782 525 0
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	February 4, 2026
Trade or Proprietary Name:	VERTICALE GPS Instruments
Device Classification Name:	Orthopedic Stereotaxic Instrument
Classification & Regulation #:	Class II per 21 CFR 882.4560
Product Code:	OLO
Classification Panel:	Restorative, Repair, and Trauma Devices (DHT6C)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

VERTICALE GPS Instruments are non-sterile, reusable instruments including awls, drills, taps, probes, burrs, and screw drivers that can be operated manually. These instruments are intended to be used with the Globus Medical Excelsius GPS® Robotic Navigation Platform to aid in implantation of Silony Medical pedicle screws (VERTICALE Posterior Spinal Fixation System and VERTICALE Cervical System). The instruments are manufactured from medical grade stainless steel.

INDICATIONS FOR USE

The VERTICALE® GPS Instruments are indicated to be used during the preparation and placement of VERTICALE® pedicle screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures for skeletally mature patients, where reference to a rigid anatomical structure such as vertebra can be identified. These instruments are designed for use with the Globus ExcelsiusGPS™ system, which is indicated for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of the safety and effectiveness. Specifically, the following characteristic are the similar between the subject and predicates:

- Device design and dimensions
- Indications for use
- Materials of manufacture
- Principles of operation

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K171651	Excelsius GPS	Globus Medical Inc.	OLO	Primary
K171421	VERTICALE ® Posterior Spinal Fixation System	Silony Medical GmbH	NKB	Reference Device
K192013	VERTICALE® Cervical System	Silony Medical GmbH	NKG	Reference Device

PERFORMANCE DATA

The VERTICALE GPS Instruments have been evaluated through an engineering analysis with geometric comparison and functional assessment of mating arrays and instrument verification compared to the Globus Excelsius instrument counterparts showing equivalent critical geometry for function and positional accuracy to predicate devices to establish the safety and efficacy for accuracy performance. The reprocessing and sterility of the VERTICALE GPS Instruments were validated per ISO 17665-1:2016. The biocompatibility of the VERTICALE GPS Instruments has been demonstrated according to the requirements of ISO 10993-1:2018. The results of the engineering analysis and non-clinical testing show that the subject is substantially equivalent to the cleared predicate.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the VERTICALE GPS Instruments are substantially equivalent to the predicate device.