June 26, 2026

Silony Medical GmbH
% Hannah Taggart
Engineer & Regulatory Specialist
ATS (Empirical Technologies)
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K253921
Trade/Device Name: VERTICALE® Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 26, 2026
Received: May 26, 2026

Dear Hannah Taggart:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Tejen D. Soni -S

For
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

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)*
K253921

Device Name
VERTICALE® Navigation Instruments

Indications for Use *(Describe)*
The VERTICALE® Navigation Instruments are indicated for use during the preparation and insertion of VERTICALE® and VERTICALE® CERVICAL screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the third party stereotactic navigation systems (Medtronic StealthStation™, Brainlab or 7D) software which are indicated for any medical condition in which the use of stereotactic surgery is suitable, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized orientation points of the anatomy.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K253921 510(k) Summary

Submitter's Name:	Silony Medical GmbH
Submitter's Address:	Leinfelder Strasse 60 70771 Leinfelden-Echterdingen Germany
Submitter's Telephone:	+49 711 7825250
Contact Person:	Hannah Taggart, MS, RAC ATS Colorado Springs 719- 457-1152 htaggart@atslab.com
Date Summary was Prepared:	June 26, 2026
Trade or Proprietary Name:	VERTICALE® Navigation Instruments
Device Classification Name:	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:

The VERTICALE® Navigation Instruments are reusable surgical instruments to assist surgeons in precisely locating anatomical structures in procedures and placement of Silony VERTICALE® Platform implants. The purpose of this submission is to add the VERTICALE® CERVICAL Navigation Instruments to the family of Silony Navigation Instruments and to add universal adapters which allow all Silony Navigation Instruments to be compatible with several navigation platforms.

The subject VERTICALE® CERVICAL Navigation Instruments are used for site preparation and insertion of implants from the VERTICALE® CERVICAL System, previously cleared via K192013. The subject VERTICALE® CERVICAL Navigation Instruments include a drill, tap, awl, driver, probe, depth stops all manufactured from Stainless Steel.

The VERTICALE® Navigation Adapters connect to the distal end of the navigation instruments and provide a connection for the tracking array of the navigation platform being used. The adapters are offered in two designs, a clamp design and a screw design. The VERTICALE® Navigation Adapters are compatible with VERTICALE® CERVICAL Navigation Instruments and VERTICALE® Thoracolumbar Navigation Instruments.

Indications for Use

The VERTICALE® Navigation Instruments are indicated for use during the preparation and insertion of VERTICALE® and VERTICALE® CERVICAL screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the third party stereotactic navigation systems (Medtronic StealthStation™, Brainlab or 7D) software which are indicated for any medical condition in which the use of stereotactic surgery is suitable, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized orientation points of the anatomy.

Technological Characteristics

The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Principles of Operation
- Sterility
- Navigation Platform
- Types of Instruments
- Implant Compatibility

Predicate Devices

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K173338	Navigated INFINITY™ Instruments	Medtronic Sofamor Danek USA, Inc.	OLO	Primary
K223649	VERTICALE® Navigation Instruments	Silony Medical GmbH	OLO	Additional

The technical characteristics of the subject VERTICALE® Navigation Instruments and universal adapters remain the same as, or similar to, the predicates in regard to indications for use, intended use, materials, and operational principles. To address any concerns for safety and efficacy due to differences in geometry of the subject instruments, accuracy testing was performed in accordance with ASTM F2554-22 *Standard Practice For Measurement of Positional Accuracy of Computer Assisted Surgical Systems.* The non-clinical verification and validation testing performed support the safety and efficacy of the VERTICALE® Navigation Instruments compatibility with the universal adapters and third-party navigation software.

Performance Data

The VERTICALE® Navigation Instruments has been tested in the following test modes:

- Single point accuracy per ASTM F2554-22
- Instrument axis rotation per ASTM F2554-22
- Instrument perpendicular plane rotation per ASTM F2554-22
- Instrument parallel plane rotation per ASTM F2554-22
- Distance between points accuracy per ASTM F2554-22
- Target Registration Error Testing
- Tool Reflectivity Testing

The results of this non-clinical testing show that the strength of the VERTICALE® Navigation Instruments is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

Conclusion

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