December 22, 2022

Silony Medical GmbH
Lisa Schwarz
Regulatory Affairs Manager
Leinfelder Straße 60
Leinfelden-Echterdingen, Baden-Württemberg D-70771
Germany

Re: K223649
Trade/Device Name: VERTICALE® Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 6, 2022
Received: December 6, 2022

Dear Lisa Schwarz:

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,

Jesse Muir -S

For: Shumaya Ali, MPH
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223649

Device Name
VERTICALE® Navigation Instruments

Indications for Use *(Describe)*
Silony Medical Navigation Instruments are intended to be used during the preparation and placement of VERTICALE® pedicle screws during spinal surgery to assist the surgeon in precise locating anatomical structures in spinal procedures. These instruments are designed for use with stereotactic navigation system Medtronic StealthStation®, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks 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.

5. 510(K) SUMMARY

Submitter's Name:	Silony Medical GmbH
Submitter's Address:	Leinfelder Straße 60 D-70771 Leinfelden-Echterdingen, Germany
Submitter's Telephone:	+49 (0) 711-782 525 0
Contact Person:	Lisa Schwarz Silony Medical GmbH +49711 78252515 LSchwarz@Silony-Medical.com
Date Summary was Prepared:	December 6th, 2022
Trade or Proprietary Name:	VERTICALE® Navigation Instruments
Common or Usual Name:	Orthopedic Stereotaxic Instrument
Classification Name:	Stereotaxic instrument
Classification:	Class II per 21 CFR 882.4560
Product Code:	OLO
Classification Panel:	Division of Orthopedic Devices
Approval procedure	Special 510(k)

DEVICE DESCRIPTION:

Silony Medical's VERTICALE® navigation instruments are reusable surgical instruments for use with the Medtronic® StealthStation® Navigation System. The system is designed to assist surgeons in the precise localization of anatomical structures, preparation and placement of pedicle screw implants during spinal procedures.

The VERTICALE® Navigation Instruments include awls, probes, taps, drivers and inserts. The VERTICALE® Navigation Instruments are to be used with the VERTICALE® Posterior Spinal Fixation System cleared under K171421.

All instruments are made of stainless steel per ASTM F899. The VERTICALE Navigation Instruments are not compatible with implants from other manufacturers and are designed for use only with Medtronic StealthStation Navigation System hardware and software.

INTENDED USE / INDICATIONS FOR USE

Silony Medical Navigation Instruments are intended to be used during the preparation and placement of VERTICALE® pedicle screws during spinal surgery to assist the surgeon in precise locating anatomical structures in spinal procedures. These instruments are designed for use with stereotactic navigation system Medtronic StealthStation®, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

SUBSTANTIAL EQUIVALENCE SUMMARY

The technological characteristics of the subject VERTICALE Navigation Instruments components remain the same as, or similar to, the predicate VERTICALE Navigation Instruments (K212007) in regards to intended use, indications for use, design, manufacturing methods and fundamental technology. The purpose of this submission is to seek clearance for four additional VERTICALE Navigation instruments for spinal surgery.

Table 5 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K212007	VERTICALE® Navigation Instruments	Silony Medical GmbH	Primary
Predicate Device from the previous 510(k); K212007			
K161210 (PRIMARY)/K143628/ K140454/K143375	Medtronic Navigated Instruments	Medtronic Sofamore Danek USA, Inc.	Reference (K212007)
K171421	VERTICALE® Posterior Spinal Fixation System	Silony Medical GmbH	Reference (K212007)

PERFORMANCE DATA

The VERTICALE Navigation Instruments have been tested per ASTM F2554-18, “Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems”.

These performance data are also applicable for the new instruments.

The additional instruments have been developed to complement Silony Medical's already approved navigable instruments (VERTICALE® Navigation Instruments; K212007) and to fully cover the intended use of the VERTICALE® Posterior Spinal Fixation System ((K171421); Section 11).

By means of a technical evaluation, the compatibility and functionality of the additional navigable instrument for spine surgery was demonstrated. Data from the already cleared navigable instruments (VERTICALE® Navigation Instruments; K212007 and Medtronic Navigated Instruments; K161210) served as the basis for the technical evaluation. The technical evaluation relates to the navigational accuracy of the instruments in terms of position verification.

As result of the verification, relevant interfaces and functionalities between the existing and the new instruments are (essentially) equivalent to the existing instruments. Therefore, the results of the verification tests (K212007) are directly transferable to the new additional instruments and repetition of these tests is not necessary.

RISK MANAGEMENT

Risk Assessment of the VERTICALE Navigation Instruments was performed in accordance with ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices. The purpose of this analysis was to identify potential new hazards and failure modes introduced by the new devices. This risk analysis resulted in the inclusion of additional references in the labeling (surgical technique).

The previous verifications and risk controls for the predicate VERTICALE Navigation Instruments (K212007) remain valid and acceptable as the controls used are unchanged by the introduction of the new instrument components presented in this submission.

The overall residual risk is acceptable and the medical benefits continue to outweigh the overall residual risk.

The Special 510(k) Program issued by the FDA on September 13, 2019 is appropriate for this submission as the proposed change is being submitted by the legal manufacturer and a risk analysis format supports substantial equivalence

SUBSTANTIAL EQUIVALENCE CONCLUSION

The new VERTICALE Navigation Instruments are substantially equivalent to the predicate system as a spinal fixation device in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and general operational principles. Furthermore, accuracy testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components to the navigated instrument system which has been cleared for stereotactic guidance during orthopedic surgery procedures.

Based on this information, the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates (K212007).