February 6, 2026

Stryker Leibinger GmbH & Co. KG
Andrea Wallen-Gerding
Principal Regulatory Affairs Specialist
Bötzinger Straße 41
Freiburg im Breisgau, D-79111
Germany

Re: K252871
Trade/Device Name: Spine Guidance 5.3 Software; Q Interbody Instruments; Elite Q Attachments; Elite Cutting Accessories
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 7, 2026
Received: January 7, 2026

Dear Andrea Wallen-Gerding:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252871

Please provide the device trade name(s).

Spine Guidance 5.3 Software; Q Interbody Instruments; Elite Q Attachments; Elite Cutting Accessories

Please provide your Indications for Use below.

Spine Guidance 5.3 Software Indications for Use:
The Q Guidance System, when used with the Spine Guidance 5 Software, is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery in adult and pediatric (adolescent) patients.
The system is indicated for orthopedic and neurological spine procedures in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intraoperative stereotaxic guidance where a reference to a rigid anatomical structure such as the skull, pelvis or spine can be identified.
The system assists in the positioning of instruments for surgical procedures on the spine and pelvis, including:

- Screw and Needle Placement in the spine or pelvis
- Bone resection in the spine
- Interbody device placement in the lumbar spine (adults only)

Q Interbody Instruments Indications for Use:
VB Spine Q Interbody Instruments are intended to be used as accessories to the Stryker Spine Guidance System to facilitate placement of VB Spine implants. They can be navigated instruments or non-navigated manual instruments. When navigated, VB Spine Q Interbody Instruments are specifically designed for use with the Spine Guidance Software. They are intended to be used with associated trackers and adaptors to facilitate preparation and placement of VB Spine interbody implants in accordance with the indications and contraindications of the associated VB Spine Implant System and/or Stryker Spine Guidance System.

Elite Q Attachments and Cutting Accessories:
The Elite Q Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE™) 2 Console and the Pi Drive 2 Motor or the Pi Drive 2 Plus Motor.
The Elite Q Attachments, when used with a compatible motor and a stereotactic instrument tracker, are also indicated as an accessory to the Stryker Spine Guidance Software.
Specific applications include but are not limited to minimally invasive spine (MIS) Spine applications, such as foraminotomy, facetectomy; orthopedic and neurological spine applications, such as corpectomy, pedicle subtraction osteotomy; and laminotomy / laminectomy.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Submitter Information

1 This Premarket Notification is submitted by:

Stryker Leibinger GmbH & Co. KG
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79111 Freiburg, Germany

2 Contact Information

Primary Contact: Andrea N. Wallen-Gerding
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Date Prepared: February 5, 2026

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3 Device Name

Table 1: Device Name

Subject (Modified) Device Information	
Trade/ Proprietary Name	➢ Spine Guidance Software (version 5.3) ➢ Q Interbody Instruments o Q Dilators o Q Adaptors o Q Calibration Device o Q Cobbs o Q Disc Cutters o Q Box Chisels o Q Stirrup Curettes ➢ Elite Q Attachments ➢ Elite Cutting Accessories
Common Name	Stereotaxic Instruments
Classification	Class II
Classification Product Code	OLO
Classification Name	Orthopedic Stereotaxic Instrument

Classification Regulation	21 CFR 882.4560
Review Panel	Orthopedic

4 Predicate Devices

The following are the legally marketed predicate devices for the subject device included in this Traditional 510(k):

Table 2: Predicate Device List

Subject Device	Predicate Device	Predicate Device 510(k)	Product Code	Manufacturer
Spine Guidance 5.3 Software (Primary)	Spine Guidance 5.2	K241171	OLO	Stryker Leibinger GmbH & Co. KG
Q Interbody Instruments	Q Pedicle Instruments	K240662	OLO	VB Spine, LLC.
Elite Q Attachments	Elite Q Attachments	K241171	OLO	Stryker Instruments
Elite Cutting Accessories	Elite Cutting Accessories	K241171	OLO	Stryker Instruments

5 Device Description

5.1 Spine Guidance 5.3 Software

The Spine Guidance 5.3 Software includes all the existing features from the Spine Guidance 5.2 Software described in K241517 as well as new features and functionality for the new software indication for interbody device (cage) placement.

New features and functionality in the Spine Guidance 5.3 Software include the following:

- New user settings where the user can select the cage family and size to be used as default in Navigation.
- New user setting to visualize instruments and implants as 3D models within the Navigation views.
- Integration and visualization of the following VB Spine Cage implant families:
  - Cascadia AN
  - Tritanium PL
  - Cascadia Lateral
- Supports and visualizes navigation enabled instruments for interbody placement workflow such as inserters, dilators, disc prep instruments, and interbody trials, as well as system components such as calibration devices and adaptors.
  - Once the instruments have been calibrated, the software can identify the instrument tip and axis and display it on the screen during Navigation.
  - When the user calibrates the interbody inserter, the cage inserter family is automatically identified by the software. The family is determined by the specific and unique length of the inserter and calibration tip.

5.2 Q Interbody Instruments

The Q Interbody Instruments in scope of this traditional 510(k) include Q Dilators, Q Disc Prep Instruments such as Q Disc Cutters, Q Box Chisels, etc. as well as new system components including the Q Long Adaptor and Q Long Adaptor Calibration Tool. The Q Interbody Instruments are intended to be used to facilitate preparation and placement of VB Spine interbody implants.

5.3 Elite Q Attachments

The Elite Q Attachments serve as the interface between the Pi Drive 2 Motors and a distally attached cutting accessory. The Elite Q Attachments provide a location for mounting a stereotactic instrument tracker and support the high-speed drill instrument tip proximity detection feature of the Spine Guidance Software.

5.4 Elite Cutting Accessories

The Elite Cutting Accessories are used for cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement, and teeth in a variety of surgical procedures. The cutting accessories can also be used in the placement or cutting of screws, metal, wires, pins, and other fixation devices. The cutting accessories support the high-speed drill instrument tip proximity detection feature of the Spine Guidance Software.

6 Indications for Use

6.1 Spine Guidance 5.3 Software

The Q Guidance System, when used with the Spine Guidance 5 Software, is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery in adult and pediatric (adolescent) patients.

The system is indicated for orthopedic and neurological spine procedures in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intraoperative stereotaxic guidance where a reference to a rigid anatomical structure such as the skull, pelvis or spine can be identified.

The system assists in the positioning of instruments for surgical procedures on the spine and pelvis, including:

- Screw and Needle Placement in the spine or pelvis
- Bone resection in the spine
- Interbody device placement in the lumbar spine (adults only)

6.2 Q Interbody Instruments

VB Spine Q Interbody Instruments are intended to be used as accessories to Stryker's Spine Guidance System to facilitate placement of VB Spine implants. They can be navigated instruments or non-navigated manual instruments. When navigated, VB Spine Q Interbody Instruments are specifically designed for use with Stryker's Spine Guidance Software. They are intended to be used with associated trackers and adaptors to facilitate preparation and placement of VB Spine interbody implants in accordance with the indications and contraindications of the associated VB Spine Implant System and/or Stryker's Spine Guidance System.

6.3 Elite Q Attachments and Cutting Accessories

The Elite Q Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE™) 2 Console and the Pi Drive 2 Motor or the Pi Drive 2 Plus Motor.

The Elite Q Attachments, when used with a compatible motor and a stereotactic instrument tracker, are also indicated as an accessory to the Stryker Spine Guidance Software.

Specific applications include but are not limited to minimally invasive spine (MIS) Spine applications, such as foraminotomy, facetectomy; orthopedic and neurological spine applications, such as corpectomy, pedicle subtraction osteotomy; and laminotomy / laminectomy.

7 Comparison of Technological Characteristics

A comparison of the technological characteristics of the subject devices included in the scope of this Traditional 510(k) is included in the tables below.

7.1 Technological Comparison between the Spine Guidance 5.3 Software and the Spine Guidance 5.2 Software

The technological comparison between the subject device (Spine Guidance 5.3 Software) and the predicate device (Spine Guidance 5.2 Software) is included in Table 6-2 below. The Spine Guidance 5.2 software application received 510(k) clearance per 510(k) number K241517.

Table 3: Technological Comparison between Spine Guidance 5.3 Software (Subject Device) and the Predicate Device

Item	Subject Device: Spine Guidance 5.3 Software	Predicate Device: Spine Guidance 5.2 Software (K241517)
Indications for Use	The Q Guidance System, when used with the Spine Guidance 5 Software, is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery in adult and pediatric (adolescent) patients. The system is indicated for orthopedic and neurological spine procedures in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intraoperative stereotaxic guidance where a reference to a rigid anatomical structure such as the skull, pelvis or spine can be identified. The system assists in the positioning of instruments for surgical procedures on the spine and pelvis, including: • Screw and Needle Placement in the spine or pelvis • Bone resection in the spine • Interbody device placement in the lumbar spine (adults only)	The Q Guidance System, when used with the Spine Guidance Software, is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery in adult and pediatric (adolescent) patients. The system is indicated for any surgical procedure on the spine in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure such as the skull, pelvis or spine can be identified. The system assists in the positioning of instruments for procedures on the pelvis and spine, including: • Screw and Needle Placement in the spine or pelvis • Bone resection in the spine
Main System Components	• Q Guidance System • Mako Spine System • Various reusable and single use instruments for use with the SG5.3 Software	• Q Guidance System • Mako Spine System • Various reusable and single use instruments for use with the SG5.2 Software

Item	Subject Device: Spine Guidance 5.3 Software	Predicate Device: Spine Guidance 5.2 Software (K241517)
Modes of Operation	• Mako Robotic Arm pre-surgery check • Patient preparation • System set-up • Image import • Planning • Patient registration • Mako Robotic Arm setup • Navigation including haptic trajectory guidance for screw placement	• Mako Robotic Arm pre-surgery check • Patient preparation • System set-up • Image import • Planning • Patient registration • Mako Robotic Arm setup • Navigation including haptic trajectory guidance for screw placement
Operating Principle	• The software is installed on the computer that is part of the platform • Images are imported in DICOM format • The software displays the images and planned items with navigational information on a monitor	• The software is installed on the computer that is part of the platform • Images are imported in DICOM format • The software displays the images and planned items with navigational information on a monitor
Planning Navigation Features	• Screws (including Screw Placement Suggestion) • Measurements • Segmentations (Manual and automatic) • Local correlation (merge regions) • Planes • Smart Zones	• Screws (including Screw Placement Suggestion) • Measurements • Segmentations (Manual and automatic) • Local correlation (merge regions) • Planes • Smart Zones
Navigation implant Features	• Screw Placement • Interbody/Cage Placement	• Screw Placement
Localizing and Tracking Technology	Infrared Optical Active and Passive Tracking	Infrared Optical Active and Passive Tracking
System Accuracy	The system has a mean accuracy of 2 mm for positional displacement and 2° for trajectory angle displacement. Accuracy values apply to tracking in the workspace.	The system has a mean accuracy of 2 mm for positional displacement and 2° for trajectory angle displacement. Accuracy values apply to tracking in the workspace.
Supported Imaging Modalities	Computed tomography (CT) Magnetic Resonance (MR) Position emission tomography (PET) 2D DICOM images (SCOUT only)	Computed tomography (CT) Magnetic Resonance (MR) Position emission tomography (PET) 2D DICOM images (SCOUT only)
Intended Use Environment	Operating Room	Operating Room

7.2 Technological Comparison between the Q Interbody Instruments and the Q Pedicle Instruments

The Q Interbody Instruments are substantially equivalent to the Q Pedicle Instruments in regard to intended use, indications for use, basic design, materials, and fundamental scientific technology.

Verification and validation testing has been completed, and the results confirm no new or different questions of safety and effectiveness have been raised. This information demonstrates that the subject devices are at least as safe and effective as their predicates and, therefore, supports a determination of substantial equivalence.

7.3 Technological Comparison between the subject and Predicate Elite Q Attachments

There have been no changes to the intended use, design, materials, fundamental scientific technology, or cleaning / sterilization processes. The Elite Q Attachments are equivalent to the predicate attachments cleared in premarket notification K241171. The only change is an update to the indications for use of the attachments to include four additional specific indications.

7.4 Technological Comparison between the subject and Predicate Elite Cutting Accessories

There have been no changes to the intended use, design, materials, fundamental scientific technology, or sterilization processes. The Elite Cutting Accessories are equivalent to the predicate cutting accessories cleared in premarket notification K241171. The only change is an update to the indications for use of the cutting accessories to include four additional specific indications.

8 Summary of Non-Clinical Testing

The function and performance of the subject devices (Spine Guidance 5.3 Software and Q Interbody Instruments) have been evaluated through non-clinical design verification and validation testing. The results of the evaluation tests demonstrate that the subject devices successfully meet the requirements of their intended use, and the subject devices demonstrate substantial equivalence to the cited predicate devices.

Additional testing was performed on the subject devices to ensure they met their design requirements. A summary of the testing and the results are included in Table 6-3 below.

- Software testing as required by IEC 62304 and FDA Guidance on General Principles of Software Validation, January 11, 2002.
- System accuracy verification per ASTM F2554-22.
- The subject devices were validated with intended users in cadaver labs or simulated use tests to ensure the user needs and intended use requirements were met. All requirements were met and no new issues of safety or effectiveness were raised.
- The subject devices were validated with intended users in cadaver labs to quantify the clinical accuracy and clinically expected error of final implant placement. All requirements were met.
- Biocompatibility verification according to ISO 10993-1:2018 and the FDA Guidance Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, September 2023.
- Sterilization validation of the reusable devices per ISO 17665-1 and the FDA Guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 2015).
- Electrical Safety and Electromagnetic Compatibility verification to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 and IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020.

9 Summary of Clinical Testing

No clinical testing was required to support this submission.

10 Conclusion

The subject devices, Spine Guidance 5.3 Software, Q Interbody Instruments, Elite Q Attachments, and Elite Cutting Accessories perform as intended and are substantially equivalent to their respective predicate device with regard to intended use, indications for use, design, principles of operation, technology, materials, and performance. No new issues of safety or effectiveness have been raised. The performance testing supports a determination of substantial equivalence.