U.S. FOOD & DRUG ADMINISTRATION

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June 6, 2024

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

Re: K240662
Trade/Device Name: Spine Guidance Software (version 5.0); Xia 3/ Serrato Q Instruments; Everest Q Instruments; Mesa 2 Q Instruments; Q Pedicle Preparation Instruments; Q S2AI Drills; Q Handles; Consolidated Operating Room Equipment (CORE) 2 Console; Electric System 6 Dual Trigger Rotary Handpiece
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 8, 2024
Received: March 8, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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.

Submission Number *(if known)*

K240662

Device Name

• Spine Guidance Software (version 5.0)
• Q Pedicle Instruments
o Xia 3 Q Taps
o Serrato Q Taps
o Xia 3/Serrato Q Screwdriver
o ES2 Q Taps
o ES2 Q Screwdriver
o Everest Q Taps
o Everest MI XT Q Taps
o Everest Q Screwdriver
o Everest MI XT Q Screwdriver
o Mesa 2 Q Taps
o Mesa 2 Q Screwdriver
o Q S2AI Drills
o Q Drills
o Q Awl
o Q Thoracic Probe
o Q Lumbar Probe
o Q Ratchet T-Handle
o Q Ratchet Round Handle
o Q Gear Shift Handle
• Consolidated Operating Room Equipment (CORE) 2 Console
• Electric System 6 Heavy Duty Dual Trigger Rotary Handpiece

Indications for Use *(Describe)*

Spine Guidance Software 5.0

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.

Q Pedicle Instruments (QPI)

Stryker Spine Q Pedicle Instruments are intended to be used as accessories to the Stryker Spine Guidance System to facilitate placement of Stryker Spine implants. They can be navigated instruments or non-navigated manual instruments. When navigated, Stryker Spine Q Pedicle Instruments are specifically designed for use with the Spine Guidance Software. They are intended to be used with a Q Navigation Adaptor and associated trackers manually or under power with a Stryker Rotary Handpiece to facilitate pedicle preparation and placement of Stryker Spine implants in the non-cervical spine in adult and pediatric (adolescent) patients in accordance with the

indications and contraindications of the associated Stryker Spine Implant System.

Consolidated Operating Room Equipment (CORE) 2 Console

The Stryker Consolidated Operating Room Equipment (CORE) 2 Console is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to orthopedic, dental, ENT (Ear, Nose, Throat), neuro, spine, and endoscopic applications. The console is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices. The CORE 2 Console is also indicated as an accessory to the Stryker Spine Guidance Software for stereotactic surgical procedures on the spine in adult and pediatric (adolescent) patients.

Electric System 6 Heavy Duty Dual Trigger Rotary Handpiece

The Stryker Electric System 6 Heavy Duty Dual Trigger Rotary Handpiece is used with the Consolidated Operating Room Equipment (CORE™) System. When used with a variety of Stryker-approved attachments, the handpiece is intended for orthopedic surgical procedures involving drilling, reaming, driving wire or pins, cutting bone and hard tissue. The Stryker Electric System 6 Heavy Duty Dual Trigger Rotary Handpiece, when used in conjunction with Stryker Spine Guidance Software, is intended to be used to facilitate preparation and placement of screws of Stryker Spine implant systems in adult and pediatric (adolescent) patients.

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 - K240662

807.92(a)(1) – Submitter Information	
510(k) Submitter:	Stryker Leibinger GmbH & Co. KG Bötzinger Straße 41 79111 Freiburg, Germany
Contact Information:	Primary: Andrea N. Wallen-Gerding Principal Regulatory Affairs Specialist (269) 491-9234 andrea.wallengerding@stryker.com Secondary: Kirsten Reinhold Senior Manager, Regulatory Affairs (201) 419-9044 kirsten.reinhold@stryker.com
Date Summary Prepared:	March 7, 2024

807.92(a)(2) – Name of Device	

Trade Name(s):	• Spine Guidance Software (version 5.0)
	• Q Pedicle Instruments
	  ○ Xia 3 Q Taps
	  ○ Serrato Q Taps
	  ○ Xia 3/Serrato Q Screwdriver
	  ○ ES2 Q Taps
	  ○ ES2 Q Screwdriver
	  ○ Everest Q Taps
	  ○ Everest MI XT Q Taps
	  ○ Everest Q Screwdriver
	  ○ Everest MI XT Q Screwdriver
	  ○ Mesa 2 Q Taps
	  ○ Mesa 2 Q Screwdriver
	  ○ Q S2AI Drills
	  ○ Q Drills
	  ○ Q Awl
	  ○ Q Thoracic Probe
	  ○ Q Lumbar Probe
	  ○ Q Ratchet T-Handle
	  ○ Q Ratchet Round Handle
	  ○ Q Gear Shift Handle
	• Consolidated Operating Room Equipment (CORE) 2 Console
	• Electric System 6 Heavy Duty Dual Trigger Rotary Handpiece

Classification Name:	Orthopedic Stereotaxic Instrument
Device Class:	Class II (21 CFR 882.4560)
Product Code(s):	OLO

807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
Spine Guidance Software, v5.0	Spine Guidance Software, v4.0, K220593
Q Pedicle Instruments	Navigated Spine Instruments, K203205, K172034
Consolidated Operating Room Equipment (CORE) 2 Console	Stryker Consolidated Operating Room Equipment (CORE) 2 Console, K171840
Electric System 6 Heavy Duty Dual Trigger Rotary Handpiece	FDA Product Code: HWE (Instrument, Surgical, Orthopedic, AC-Powered Motor and Accessory/ Attachment) Regulation Number: 878.4820

807.92(a)(4) – Device Description

Spine Guidance 5.0 System Overview

The Spine Guidance 5.0 system is an image guided stereotaxic, planning, and intraoperative guidance system intended to enable open or percutaneous computer-assisted surgery. It assists the surgeon in precisely positioning manual and powered instruments and locating patient anatomy during spinal surgery.

The system is comprised of the Spine Guidance 5.0 Software, the Q Guidance System (computer platform), navigated accessories/ instruments (e.g., powered drills, pointers), and various system components (e.g., calibration devices, navigation adaptors, patient/ instrument trackers, etc.). The system provides intraoperative guidance to the surgeon using passive and active wireless optical tracking technologies. The computer platform consists of a computer, camera, big touchscreen monitor, and a small touchscreen monitor. The Spine Guidance 5.0 software functionality is described in terms of its capabilities that feature planning, registration, and navigation of medical devices,

The following new instrumentation can be used with the system:

- The Q Pedicle Instruments are intended to be used to facilitate pedicle preparation and screw placement of Stryker Spine implant systems.
- The CORE 2 Console has three handpiece ports, two footswitch ports, and one irrigation cassette port. The console supplies power to devices for a variety of surgical procedures as described in its indications for use. It is comprised of a power supply, central processing unit, motor controller, irrigation pump controller, RFID module, liquid crystal display (LCD) screen and speaker for output, touch screen for user input, USB port, and an Ethernet port. The CORE 2 software contains an optional depth-stop feature driven by Spine Guidance 5 Software.
- The ES 6 Heavy Duty Dual Trigger Rotary Handpiece is used in drilling, reaming and decorticating of bone and other bone related tissue in a variety of surgical procedures. It is also usable in the placement of screws, wires, pins, and other fixation devices. This handpiece supports the depth-stop feature.

This system is for professional use only within a professional healthcare environment.

807.92(a)(5) – Intended Use of the Device

Indications for Use:

Spine Guidance Software 5.0

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.

Q Pedicle Instruments (QPI)

Stryker Spine Q Pedicle Instruments are intended to be used as accessories to the Stryker Spine Guidance System to facilitate placement of Stryker Spine implants. They can be navigated instruments or non-navigated manual instruments. When navigated, Stryker Spine Q Pedicle Instruments are specifically designed for use with the Spine Guidance Software. They are intended to be used with a Q Navigation Adaptor and associated trackers manually or under power with a Stryker Rotary Handpiece to facilitate pedicle preparation and placement of Stryker Spine implants in the non-cervical spine in adult and pediatric (adolescent) patients in accordance with the indications and contraindications of the associated Stryker Spine Implant System.

Consolidated Operating Room Equipment (CORE) 2 Console

The Stryker Consolidated Operating Room Equipment (CORE) 2 Console is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to orthopedic, dental, ENT (Ear, Nose, Throat), neuro, spine, and endoscopic applications. The console is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

The CORE 2 Console is also indicated as an accessory to the Stryker Spine Guidance Software for stereotactic surgical procedures on the spine in adult and pediatric (adolescent) patients.

Electric System 6 Heavy Duty Dual Trigger Rotary Handpiece

The Stryker Electric System 6 Heavy Duty Dual Trigger Rotary Handpiece is used with the Consolidated Operating Room Equipment (CORE™) System. When used with a variety of Stryker-approved attachments, the handpiece is intended for orthopedic surgical procedures involving drilling, reaming, driving wire or pins, cutting bone and hard tissue.

The Stryker Electric System 6 Heavy Duty Dual Trigger Rotary Handpiece, when used in conjunction with Stryker Spine Guidance Software, is intended to be used to facilitate preparation and placement of screws of Stryker Spine implant systems in adult and pediatric (adolescent) patients.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

Characteristic	Subject Device	Predicate Device
Indication(s)	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	The Stryker 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 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 spine, pelvis or skull can be identified. The system assists in the positioning of instruments for procedures on the spine and pelvis, including: • Screw Placement in the spine or pelvis
Main System Components	• Q Guidance System • Navigated Instruments • System accessories and components	• Q Guidance System • Navigated Instruments • System accessories and components
Modes of Operation	• Patient Preparation • System Set-up • Image Import • Planning • Patient Registration • Navigation	• Patient Preparation • System Set-up • Image Import • Planning • Patient Registration • Navigation
Localizing and Tracking	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)
Planning Features	• Screws • Measurements • Trajectories • Segmentations (Manual and automatic) • Merge Levels (local correlation)	• Screws • Measurements • Trajectories • Segmentations (Manuel and automatic) • Merge Levels (local correlation) • Image merge
Registration Features	• Anatomical (Point-to-Point) Registration • Surface Registration • 3D CT/ C-Arm Registration • Automatic Intraoperative Mask Registration	• Anatomical (Point-to-Point) Registration • Surface Registration • 3D CT/ C-Arm Registration • Automatic Intraoperative Mask Registration • Mask Registration
Intended Use Environment	Operating Room (OR)	Operating Room (OR)
Output	3D image Analog and Digital Video Images	3D image Analog and Digital Video Images
• Graphical User Interface	• Black-style graphical user interface • 16:9 screen ratio • Case Dashboard to access all operation modes • One tab per task concept from left to right on top of screen • Image box with image tools • Current task panel on the right or bottom • Image settings task panel on the left	• Black-style graphical user interface • 16:9 screen ratio • Case Dashboard to access all operation modes • Image box with image tools • Current task panel on the right • Image settings task panel on the left
• User Interface	• Large touch monitor • Small touch monitor • Keyboard • Mouse • Buttons on active optical instruments	• Large touch monito • Small touch monitor • Keyboard • Mouse • Buttons on active optical instruments

Technological Comparison between the Navigated Q Pedicle Instruments and their predicate devices

The navigated Q Pedicle Instruments in scope of this traditional 510(k) have similar designs, materials, intended use, sterilization, and fundamental scientific technology to their predicate devices and system

components. The modifications to the instruments do not adversely impact the technological characteristics of the predicate devices.

Technological Comparison between the CORE 2 Console and its predicate device
There have been no changes made to the intended use, materials, or fundamental scientific technology of the CORE 2 Console. The device has undergone a software modification to enable communication with the Spine Guidance 5.0 Software System. The indications for use have also been updated to allow use with the Spine Guidance 5 Software.

Technological Comparison between the Electric System 6 and its predicate device
There have been no changes to the intended use, design, materials, fundamental scientific technology, or sterilization process. The only update is to the indication for use to allow it to be used with the Spine Guidance 5 Software.

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807.92(b)(1) – Nonclinical Testing to Support Submission

The function and performance of the subject devices have been evaluated through non-clinical design verification and validation testing. Additional testing was performed on the subject devices to ensure they met their design requirements. The results of the evaluation tests demonstrate that the subject devices successfully meet the requirements of their intended use.

Accuracy
System demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0mm and in trajectory angle accuracy with a mean error ≤ 2.0 degrees. This performance was determined using anatomically representative phantoms and utilizing a subset of system components and features that represent the worst-case combinations of all potential system components.

Software

Software verification and validation testing was conducted as required by IEC 62304 and FDA Guidance on General Principles of Software Validation, January 11, 2002. All requirements were met, and no new issues of safety or effectiveness were raised.

Biocompatibility

The biocompatibility of all patient contact materials was verified 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. No new issues of safety or effectiveness were raised.

Electrical Safety and Electromagnetic Compatibility

Verified conformance to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020.

Verified conformance to IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, CISPR 11 Group 1, Class A requirements as well as additional testing to verify compatibility with RFID devices operating in the 125 - 134 kHz and 13.56 MHz frequency band.

Sterilization

The reusable subject devices underwent a steam sterilization validation to demonstrate that they can be expected to be sterile and have a sterility assurance level (SAL) of 10-6 or greater after processing.
The Tracking Instrument Battery underwent gamma sterilization validation per ISO 11137-2: 2013/(R) 2019 to demonstrate that they can be expected to be sterile and have a sterility assurance level (SAL) of 10-6

807.92(b)(2) – Clinical Testing
No clinical testing was required to support this submission.

807.92(b)(3) – Conclusions Drawn from Testing Performed
Results of performance testing were determined successful for all protocols and demonstrate that the functionality, integrity, and safety and effectiveness of the subject devices are sufficient for their intended use. Performance test results for the subject devices demonstrate substantial equivalent to the predicate devices.

Conclusion/ Substantial Equivalence (SE) Rationale:
The subject device, in comparison with the legally marketed predicate, has the same intended use, indications for use, operating principles, energy source, and functional outputs. Performance testing and risk analysis demonstrate that the device is as safe and effective as the predicate device and supports the determination of substantial equivalence.