July 25, 2024

Stryker Leibinger GmbH & Co. KG
John Chesney
Sr. Principal Regulatory Affairs Specialist
Botzinger Strasse 39-41
Freiburg Baden-Wurttemberg, D-79111
Germany

Re: K241171
Trade/Device Name: Spine Guidance Software (Version 5.1); Consolidated Operating Room Equipment (CORE) 2 Console; CORE Q Footswitch; PI Drive 2 Motors; Elite Q Attachments and Cutting Accessories
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HWE
Dated: April 26, 2024
Received: April 26, 2024

Dear John Chesney:

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,

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

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)*

K241171

Device Name

Spine Guidance Software (Version 5.1);
Consolidated Operating Room Equipment (CORE) 2 Console;
CORE Q Footswitch;
PI Drive 2 Motors;
Elite Q Attachments and Cutting Accessories

Indications for Use *(Describe)*

Spine Guidance 5.1 Software

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

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 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.

CORE Q Footswitch

The CORE Q Footswitch is an accessory to the CORE 2 Console. When the pedal is actuated, it provides a signal to the console for variable speed control of the handpiece connected to the console.
The footswitch is intended for use in surgical spine procedures. When used with the Stryker Spine Guidance Software, the footswitch when commanded by the console provides haptic feedback based upon user defined spatial boundaries.

Pi Drive 2 Motors

The Pi Drive 2 and Pi Drive 2 Plus Motors are intended for use with the Stryker® Consolidated Operating Room Equipment (CORE™) System. The motors, when used with a compatible Elite Q Attachment and a stereotactic instrument tracker, are also indicated as an accessory to the Stryker

Spine Guidance Software.

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 laminotomy / laminectomy, minimally invasive surgery (MIS) spine, and orthopedic spine.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K241171

807.92(a)(1) – Submitter Information	
510(k) Submitter:	Stryker Leibinger GmbH & Co. KG Bötzinger Straße 41 79111 Freiburg, Germany
Contact Information:	Primary: John Chesney Sr. Principal Regulatory Affairs Specialist (734)673-5624 john.chesney@stryker.com Secondary: Louise Keane Manager, Regulatory Affairs louise.keane@stryker.com
Date Summary Prepared:	26 April 2024

807.92(a)(2) – Name of Device	
Trade Name(s):	• Spine Guidance Software (version 5.1) • CORE 2 Console • CORE Q Footswitch • Pi Drive 2 Motors • Elite Q Attachments and Cutting Accessories
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 (version 5.1)	Spine Guidance Software (version 5.0) – K240662 (Primary)
CORE 2 Console	CORE 2 Console – K240662
CORE Q Footswitch	TPS Uni-Directional Footswitch – K112593
Pi Drive 2 Motors	Pi Drive 2 Motors – K211490
Elite Q Attachments	Elite Q Attachments – K190172
Elite Cutting Accessories	Elite Cutting Accessories – K112593

807.92(a)(4) – Device Description

Spine Guidance 5.1 System Overview

The Spine Guidance 5.1 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 5.1 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 5.1 Software functionality is described in terms of its capabilities that feature planning, registration, and navigation of medical devices. The following new or modified instrumentation can be used with the system:

- 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 supports the optional high-speed drill instrument tip proximity detection feature as well as the audible and haptic feedback modalities driven by the Spine Guidance 5.1 Software.
- The CORE Q Footswitch connects to the CORE 2 Console and is used to control a high-speed drill. The footswitch can provide haptic feedback to the user when set as a notification modality when using Spine Guidance 5.1 Software.
- The Pi Drive 2 Motors are used with a CORE 2 Console and a compatible attachment and cutting accessory for cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures. The motors are also usable in the placement or cutting of screws, metals, wires, pins, and other fixation devices. The motors support the high-speed drill instrument tip proximity detection feature.
- 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.
- 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.

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 5.1 Software

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

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 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.

CORE Q Footswitch

The CORE Q Footswitch is an accessory to the CORE 2 Console. When the pedal is actuated, it provides a signal to the console for variable speed control of the handpiece connected to the console.

The footswitch is intended for use in surgical spine procedures. When used with the Stryker Spine Guidance Software, the footswitch when commanded by the console provides haptic feedback based upon user defined spatial boundaries.

Pi Drive 2 Motors

The Pi Drive 2 and Pi Drive 2 Plus Motors are intended for use with the Stryker® Consolidated Operating Room Equipment (CORE™) System.

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

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 laminotomy / laminectomy, minimally invasive surgery (MIS) spine, and orthopedic spine.

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 • Bone resection in the spine	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

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) • 2D DICOM images (SCOUT only)
Planning Features	• Screws • Measurements • Trajectories • Segmentations (Manual and automatic) • Merge Levels (local correlation) • Smart Zones	• Screws • Measurements • Trajectories • Segmentations (Manual and automatic) • Merge Levels (local correlation)
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
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	• 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	• Current task panel on the right or bottom • Image settings task panel on the left
User Interface	• Large touch monitor • Small touch monitor • Keyboard • Mouse • Buttons on active optical instruments	• Large touch monitor • Small touch monitor • Keyboard • Mouse • Buttons on active optical instruments

Technological Comparison between the CORE 2 Console and its predicate device
There have been no changes made to the intended use, indications for use, design, materials, or fundamental scientific technology of the CORE 2 Console. The device has undergone a software modification to enable use of the Pi Drive 2 Motors and CORE Q Footswitch with the Spine Guidance 5.1 Software System.

Technological Comparison between the CORE Q Footswitch and its predicate device
There are no changes to the intended use, design, or fundamental scientific technology between the subject and predicate devices. The subject device introduces a motor which provides haptic feedback to the user when used with Spine Guidance 5.1 Software.

Technological Comparison between the Pi Drive 2 Motors and their predicate device
There have been no changes to the intended use, design, materials, fundamental scientific technology, or cleaning / sterilization processes. The only change is an update to the indications for use for the motors reflecting their use as an accessory with Spine Guidance 5.1 Software.

Technological Comparison between the Elite Q Attachments and their predicate device
There are no changes to the intended use, materials, or fundamental scientific technology between the subject and predicate devices. The attachments include a design modification which incorporates an extension beam for mounting of a stereotaxic tracker (CoPilot Q 360 Tracker) to enable use with the Spine Guidance 5.1 Software.

Technological Comparison between the Elite Cutting Accessories and their predicate device
There have been no changes to the intended use, design, materials, fundamental scientific technology, or sterilization process. The only update is to their indications for use reflecting their use as an accessory with Spine Guidance 5.1 Software.

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 ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0°. 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.

Sterilization

The reusable subject devices have undergone steam sterilization validation to ensure they can meet a sterility assurance level (SAL) of 10^{-6}.

The Elite Cutting Accessories have undergone gamma sterilization validation per ISO 11137-2: 2013/(R) 2019 to ensure they can meet 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 devices, in comparison with the legally marketed predicates, have the same or equivalent intended use, indications for use, operating principles, energy source, and functional outputs. Performance testing and risk analysis demonstrate that the devices are as safe and effective as their predicate devices and support a determination of substantial equivalence.