May 27, 2022

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

Re: K220593
Trade/Device Name: Spine Guidance Software, Q Guidance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 28, 2022
Received: March 1, 2022

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 (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,

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K220593

Device Name
Spine Guidance Software

Indications for Use *(Describe)*

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 (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 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

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."*

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)*
K220593

Device Name
Q Guidance System

Indications for Use *(Describe)*

The Q Guidance System is intended as an aid for precisely locating anatomical structures in open or percutaneous computer assisted surgery. The system is indicated for any medical condition in which the use of computer assisted planning and surgery may be appropriate and where reference to a rigid anatomical structure such as the skull, vertebra, or long bone can be identified.

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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# 6.0 Submitter Information

## 6.1 This Premarket Notification is submitted by:

Stryker Leibinger GmbH & Co. KG
Bötzinger Straße 41
79111 Freiburg, Germany

## 6.2 Contact Information

Contact Name: Andrea N. Wallen-Gerding

Cell Telephone: (269) 491-9234

Email: andrea.wallengerding@stryker.com

Date Prepared: February 28, 2022

## 6.3 Device Name

**Table 6-1: Device Name**

| **Subject (Modified) Device Information** | |
|---|---|
| **Trade/ Proprietary Name** | Spine Guidance Software<br>Q Guidance System |
| **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 |

## 6.4 Predicate Devices

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

**Table 6-2: Predicate Device List**

| Subject Device | Predicate Device Trade Name | 510(k) | Product Code | Manufacturer |
|---|---|---|---|---|
| Spine Guidance 4.0 Software | SpineMap 3D 3.1 Software | K172034 [Primary] | OLO | Stryker Leibinger GmbH & Co. KG |
| Stryker Q Guidance System | Stryker NAV3i Platform | K162341 | OLO | Stryker Leibinger GmbH & Co. KG |

## 6.5 Device Description

### 6.5.1 Stryker Q Guidance System with Spine Guidance 4.0 Software System Overview

The Stryker Q Guidance System with Spine Guidance 4.0 Software system is a computer-assisted stereotaxic, image-guided, planning, and intraoperative guidance system intended to enable open or percutaneous computer-assisted surgery. It assists the surgeon in precisely positioning instruments and locating patient anatomy during spinal surgery.

The Q Guidance System with Spine Guidance 4.0 Software system is comprised of a computer platform, Spine Guidance Software, navigated accessories/ instruments (e.g., patient/ instrument trackers, pointers), and various system components (i.e. Calibration Body, Registration Pointer, 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 4.0 Software is dedicated to spine surgical procedures as defined in the indications for use. Required navigated instruments include a patient tracker, an instrument tracker, pointers, etc. An instrument battery is required when a battery powered instrument or calibration device is used.

The Spine Guidance 4.0 Software displays the intraoperative location of navigated surgical instruments relative to imported patient medical images via wireless optical tracking technology. The software provides the functions to perform the indicated navigated spine surgical procedures. The software guides the user through the necessary preoperative and intraoperative steps required to set-up and perform the navigated spine surgical procedures.

The Spine Guidance 4.0 Software system includes the system components described below.

- Flat Disc Stick-On Fiducials

  The Flat Disc Stick-On Fiducials are passive imaging device trackers designed specifically for use with the AIRO Mobile TruCT System. The Flat Disc Stick-On Fiducials combine to form a

passive tracker used for automatically registering patient image data with the patient tracker in place.

- Calibration Body

  The Calibration Body is used to validate and calibrate active and passive optically navigated instruments when used with the Spine Guidance Software system.

- Registration Pointer

  The Registration Pointers are optional accessories to the Spine Guidance Software. They include pins for the connection of reflective spheres that allow them to be tracked by the Spine Guidance Software system.

- Mayfield Base with Articulating Arm

  The Mayfield Base with Articulating Arm has a mechanical interface to the starburst connection on skull clamps. A Universal Tracker or an nGenius Universal Tracker can be attached to the Mayfield Base with Articulating Arm to enable tracking by the Spine Guidance Software system.

## 6.6 Indications for Use

### 6.6.1 Stryker Q Guidance System

The Q Guidance System is intended as an aid for precisely locating anatomical structures in open or percutaneous computer assisted surgery. The system is indicated for any medical condition in which the use of computer assisted planning and surgery may be appropriate and where reference to a rigid anatomical structure such as the skull, vertebra, or long bone can be identified.

### 6.6.2 Spine Guidance 4.0 Software

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 (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 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

## 6.7 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.

### 6.7.1 Technological Comparison between the Stryker Spine Guidance 4.0 Software System and the Stryker SpineMap 3D 3.1 Software System

The technological comparison between the subject device (Stryker Spine Guidance Software System) and the predicate device (SpineMap 3D 3.1 Software System) is included in Table 6-3 below. The Stryker Navigation System with SpineMap 3D 3.1 software application received 510(k) clearance per 510(k) number K172034.

**Table 6-3: Technological Comparison between Stryker Q Guidance System with Spine Guidance 4.0 Software (Subject Device) and the Predicate Device**

| Item | Subject Device:<br>Stryker Q Guidance System with Spine Guidance 4.0 Software | Predicate Device:<br>Stryker Navigation System with SpineMap 3D 3.1 Software Application (K172034) |
|---|---|---|
| **Indications for Use** | 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.<br><br>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.<br><br>The system assists in the positioning of instruments for procedures on the spine and pelvis, including:<br>• Screw Placement in the spine or pelvis | The Stryker Navigation System, when used with the SpineMap 3D software application, is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery.<br><br>The system is indicated for any medical condition 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 pelvis or spine can be identified.<br><br>The system assists in the positioning of instruments for procedures on the pelvis and spine, including:<br>• Screw Placement in the spine, ilium, or pelvis |
| **Main System Components** | • Q Guidance System<br>• Spine Guidance 4.0 Software<br>• Navigated Instruments<br>• System accessories and components | • NAV3 Platform Family<br>• SpineMap 3D 3.1 Software<br>• Navigated Instruments<br>• System accessories and components |
| **Modes of Operation** | • Patient Preparation<br>• System Set-up<br>• Image Import<br>• Planning<br>• Patient Registration<br>• Navigation | • Patient Preparation<br>• System Set-up<br>• Image Import<br>• Planning<br>• Patient Registration<br>• Navigation |

| Item | Subject Device:<br>Stryker Q Guidance System with Spine Guidance 4.0 Software | Predicate Device:<br>Stryker Navigation System with SpineMap 3D 3.1 Software Application (K172034) |
|---|---|---|
| **Localizing and Tracking Technology** | Infrared Optical Active Tracking:<br>Infrared light emitted by diodes placed in specific locations on tracked instruments is sensed by the navigation camera on the platform, which allows for computation of the position and orientation of the tracked instruments.<br><br>Infrared Optical Passive Tracking:<br>Infrared light from reflective navigation spheres or discs in specific locations on tracked instruments or imaging devices are sensed by the navigation camera on the platform, which allows for computation of the position and orientation of the tracked instruments. The navigation camera sends out regular infrared light pulses which are reflected by the navigation spheres on the tracked instruments. | Infrared optical active sensing technology: Infrared light emitted by diodes placed in specific locations on navigated surgical instruments is sensed by a camera array (navigation camera) on the platform, which allows for computation of the spatial information |
| **Operating Principle** | • The software is installed on the computer that is part of the platform<br>• Images are imported in DICOM format<br>• 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<br>• Images are imported in DICOM format<br>• The software displays the images and planned items with navigational information on a monitor |
| **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)<br>• Computed tomography angiography (CTA)<br>• Magnetic resonance (MR)<br>• Magnetic resonance angiography (MRA)<br>• Position emission tomography (PET) | • Computed tomography (CT)<br>• Computed tomography angiography (CTA)<br>• Magnetic resonance (MR)<br>• Magnetic resonance angiography (MRA)<br>• Position emission tomography (PET) |
| **Planning Features** | • Screws<br>• Measurement<br>• Trajectories<br>• Automatic Segmentation<br>• Manual Segmentation<br>• Merge Levels (Local Correlation)<br>• Image Merge | • Screws<br>• Measurements<br>• Planes<br>• Annotation Points<br>• Trajectories<br>• Manual Segmentation<br>• Anatomical Systems<br>• Local Correlation<br>• Image Merge |

| Item | Subject Device:<br>Stryker Q Guidance System with Spine Guidance 4.0 Software | Predicate Device:<br>Stryker Navigation System with SpineMap 3D 3.1 Software Application (K172034) |
|---|---|---|
| | | • 3D Models<br>• Compositions |
| **Registration Features** | • Anatomical (Point-to-Point) Registration<br>• Surface Registration<br>• 3D CT/ C-Arm Registration<br>• Automatic Intraoperative Mask Registration which includes AIM Fallback Workflow<br>• Mask Registration | • Anatomical (Point-to-Point) Registration<br>• Surface Registration<br>• 3D C-Arm Registration<br>• Automatic Intraoperative Mask (AIM) Registration which includes the AIM Fallback Workflow<br>• Mask Registration |
| **Energy Source** | • Main Power: Alternating Current (AC) power supply, 100/240 V and 50/60 Hz<br>• Uninterruptable Power supply with battery support for 6 minutes | • Main Power: Alternating Current (AC) power supply, 100/240 V and 50/60 Hz<br>• Off-the-Shelf uninterruptable power supply for power interruptions ≤ 6 minutes |
| **Intended Use Environment** | Operating Room (OR) | Operating Room (OR) |
| **Input** | • Analog Video Input (AVI)<br>• Digital Video Input (DVI)<br>• Ethernet<br>• USB | • Analog Video Input (AVI)<br>• Ethernet<br>• USB |
| **Output** | • 3D image<br>• Analog and Digital Video Images (e.g., endoscopy, target guidance image) | • 3D image,<br>• Anatomic orthogonal images,<br>• Analog video image (e.g., endoscopy, target guidance image) |
| **Graphical User Interface** | • Black-style graphical user interface<br>• 16:9 screen ratio<br>• Case Dashboard to access all operation modes<br>• Image box with image tools<br>• Current task panel on the right<br>• Image settings task panel on the left | • Black-style graphical user interface<br>• 16:9 screen ratio<br>• One tab per task concept from left to right on top of screen<br>• Image box with image tools<br>• Current task panel on the right |
| **User Interface** | • Large touch monitor<br>• Small touch monitor<br>• Keyboard<br>• Mouse<br>• Buttons on active optical instruments | • Monitor with resolution display screen<br>• Virtual keyboard<br>• Mouse<br>• IO Tablet with touch screen, USB ports, and CD/DVD drive<br>• Buttons on Navigated Instruments |

## 6.8 Summary of Non-Clinical Testing

The function and performance of the subject devices (i.e., Stryker Q Guidance System with Spine Guidance Software (including the system components listed above) 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.

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 the table below.

<table>
<tr><th>Item</th><th>Summary of Testing</th></tr>
<tr><td>Intended Use/ User Needs</td><td>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.</td></tr>
<tr><td>Accuracy</td><td>The System is designed to work in the working space with a mean accuracy of 2 mm point and 2° angular axis displacement within the registration zone. The 95th percentile of the point displacement is ≤ 3 mm and ≤ 3° for angular axis displacement within the registration zone.
<table>
<tr><th></th><th>Positional Displacement (mm)</th><th>Trajectory Angle Displacement (degrees)</th></tr>
<tr><td>99% Confidence Interval (Upper)</td><td>2.60</td><td>1.78</td></tr>
<tr><td>Mean</td><td>1.32</td><td>0.73</td></tr>
<tr><td>Standard Deviation</td><td>0.52</td><td>0.43</td></tr>
</table></td></tr>
<tr><td>Safety</td><td>Verified the effectiveness of all risk controls determined in the device risk analysis. No new issues of safety or effectiveness were raised.</td></tr>
<tr><td>General Requirements and Performance</td><td>Verified all components against their design specifications. All requirements were met and no new issues of safety or effectiveness were raised.</td></tr>
<tr><td>Software</td><td>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.</td></tr>
<tr><td>Biocompatibility</td><td>The biocompatibility of all patient contact materials was verified according to ISO 10993-1:2018 and FDA guidance on the use of ISO 10993-1, September 2020. No new issues of safety or effectiveness were raised.</td></tr>
<tr><td>Electrical Safety</td><td>Verified conformance to IEC 60601-1: 2005, COR. 1:2006, COR. 2:2007, AMD 1:2012 (equivalent to IEC 60601-1:2012 Reprint).</td></tr>
<tr><td>Electromagnetic Compatibility</td><td>Verified conformance to IEC 60601-1-2: 2014, CISPR 11 Group 1, Class A requirements as well as additional testing to verify</td></tr>
</table>

| Item | Summary of Testing |
|---|---|
| | compatibility with RFID devices operating in the 125 - 134 kHz and 13.56 MHz frequency band. |
| **Shipping** | The functionality of the devices after simulated shipping conditions was verified. No new issues of safety or effectiveness were raised. |
| **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. All requirements were met and no new issues of safety or effectiveness were raised. |

## 6.9 Summary of Clinical Testing

No clinical testing was performed.

## 6.10 Conclusion

The subject devices, Stryker Q Guidance System and Spine Guidance 4.0 Software, including the system components described above, perform as intended and are substantially equivalent to their respective predicate device with regard to intended use, design, principles of operation, technology, materials, and performance. No new issues of safety or effectiveness have been raised.