September 10, 2024

Stryker Leibinger GmbH & Co. KG
Dipan Lad
Senior Staff Regulatory Affairs Specialist
Bötzinger Straße 41
Freiburg Baden-Wurttembe, D-79111
Germany

Re: K241517
Trade/Device Name: Spine Guidance Software (version 5.2); Mako Spine System; System 8 Rotary Handpiece
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO

Dear Dipan Lad:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 29, 2024. Specifically, FDA is updating this SE Letter to modify the device trade name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shumaya Ali, M.P.H., OHT6: Office of Orthopedic Devices, (301) 796-2356, shumaya.ali@fda.hhs.gov.

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

August 27, 2024

Stryker Leibinger GmbH & Co. KG
Dipan Lad
Senior Staff Regulatory Affairs Specialist
Bötzinger Straße 41
Freiburg Baden-Wurttembe, D-79111
Germany

Re: K241517
Trade/Device Name: Q Guidance System; Mako Spine System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 29, 2024
Received: May 29, 2024

Dear Dipan Lad:

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)*

K241517

Device Name

Spine Guidance Software (version 5.2);
Mako Spine System;
System 8 Rotary Handpiece

Indications for Use *(Describe)*

Spine Guidance 5.2 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

Mako Spine System
The Mako Spine System is intended to be used as an accessory to the Stryker Spine Guidance System. It is intended to be used to facilitate preparation and placement of screws of Stryker Spine implants in the non-cervical spine in adult and pediatric (adolescent) patients.
The Mako Spine System is intended to be used as part of the Stryker Spine Guidance System, which 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 or pelvis can be identified.

System 8 Rotary Handpiece
The Stryker System 8 Dual Trigger Rotary Battery Powered Heavy Duty System is intended for use in the drilling, reaming, and decorticating of bone and other bone related tissue in a variety of surgical procedures. They are also usable in the placement of screws, wires, pins, and other fixation devices.
The Stryker System 8 Dual Trigger Rotary Battery Powered Heavy Duty System, 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

- **Sponsor Information**

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

Contact Person: Dipan Lad
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Alternate Contact: Kirsten Reinhold
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Date Prepared: May 29, 2024

- **Subject Device Information**

Table 6-1: Subject Device Information

Subject (Modified) Device Information	
Trade/ Proprietary Name	➢ Spine Guidance Software (version 5.2) ➢ Mako Spine System ➢ System 8 Rotary Handpiece
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

- **Predicate Devices**
  - The following are the legally marketed predicate devices to which substantial equivalence is claimed:
    - Spine Guidance Software (version 5.1) – K241171
    - Mako Total Knee Application – K241011
    - System 8 Rotary Handpiece – Class I Exempt (Product Code: HWE)
  - Legally marketed reference device used to support substantial equivalence in terms of using robotic arm in spine procedure for trajectory guidance:
    - Mazor X – K203005

- **Device Description**
  - **Spine Guidance 5.2 Software**

    The Spine Guidance System is a computer-assisted stereotaxic, image-guided, planning, and intraoperative guidance system intended to enable open or percutaneous computer-assisted surgery on the spine and pelvis. 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 5.2 Software, Q Guidance System (computer platform), Mako Spine System, navigated accessories/ instruments (e.g., patient/ instrument trackers, pointers), and various system components (e.g., trackers, calibration instruments, etc.).

    The system provides intraoperative guidance to the surgeon using passive and active wireless optical tracking technologies as well as haptic trajectory guidance to facilitate pedicle preparation and screw placement using Mako Spine System.

    The Spine Guidance 5.2 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.

  - **Mako Spine System**

    The Mako Spine System is an accessory to the subject Spine Guidance 5.2 (SG5.2) Software and extends the functionality of the SG5.2 Software to provide trajectory guidance to align the End Effector tube with a pre-planned screw trajectory to facilitate preparation and placement of screws in the non-cervical spine. The Mako Spine System includes a Mako 3.5 Robotic arm, new dedicated instrumentations (i.e. Spine Pedicle End Effector, Spine Pedicle Registration Tool, Q Pedicle Instruments, etc.), and previously cleared compatible instruments (i.e. Vizadisc, Rio System Quick Connect Base Array, End Effector Tracker Array, Calibration End-Effector, etc.). Mako 3.5 Robotic Arm is connected to the existing Q Guidance System (K233542) via Mako ethernet cable.

  - **System 8 Rotary Handpiece**

    The System 8 Dual Trigger Rotary Handpiece is used in the drilling, reaming, and decorticating of bone and other bone related tissue in a variety of surgical procedures. It is also used in the placement of screws, wires, pins, and other fixation devices. The handpiece, when used with a compatible instrument tracker, can be used with the Spine Guidance 5.2 Software to facilitate preparation and placement of screws using Stryker Spine implant systems.

- **Intended Use/ Indications for Use**
  - **Spine Guidance 5.2 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

  - **Mako Spine System**

    The Mako Spine System is intended to be used as an accessory to the Stryker Spine Guidance System. It is intended to be used to facilitate preparation and placement of screws of Stryker Spine implants in the non-cervical spine in adult and pediatric (adolescent) patients.

    The Mako Spine System is intended to be used as part of the Stryker Spine Guidance System, which 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 or pelvis can be identified.

  - **System 8 Rotary Handpiece**

    The Stryker System 8 Dual Trigger Rotary Battery Powered Heavy Duty System is intended for use in the drilling, reaming, and decorticating of bone and other bone related tissue in a variety of surgical procedures. They are also usable in the placement of screws, wires, pins, and other fixation devices.

    The Stryker System 8 Dual Trigger Rotary Battery Powered Heavy Duty System, 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.

- **Summary of Technological Characteristics**

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

  - **The technological comparison between the subject device (Spine Guidance 5.2 Software) and the predicate device (Spine Guidance 5.1 Software)**:

Table 6-2: Technological Comparison between Spine Guidance 5.2 Software (Subject Device) and the Predicate Device

Item	Subject Device: Spine Guidance 5.2 Software	Predicate Device: Spine Guidance 5.1 Software (K241171)
Indications for Use	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 • Bone resection in the spine
Main System Components	• Q Guidance System • Mako Spine System • Various reusable and single use instruments for use with the SG5.2 Software	• Q Guidance System • Various reusable and single use instruments for use with the SG5.1 Software
Modes of Operation	• Mako 3.5 Robotic Arm pre-surgery check • Patient preparation • System set-up • Image import • Planning • Patient registration • Mako 3.5 Robotic Arm setup • Navigation including haptic trajectory guidance	• Patient preparation • System set-up • Image import • Planning • Patient registration • Navigation
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 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

- **The technological comparison between the subject device (Mako Spine System) and the predicate device (Mako Total Knee Application):**

Table 6-3: Technological Comparison between the Mako Spine System (Subject Device) and the Predicate Device

Item	Subject Device: Mako Spine System	Predicate Device: Mako Total Knee Application (K241011)
Indications for Use	The MAKO System is intended to be used as an accessory to the Stryker Spine Guidance System. It is intended to be used to facilitate preparation and placement of screws of Stryker Spine implants in the non-cervical spine in adult and pediatric (adolescent) patients. The MAKO System is intended to be used as part of the Stryker Spine Guidance System, which 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 or pelvis can be identified.	The Mako System is indicated for use in surgical knee and hip procedures in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include: • Total Knee Arthroplasty
Major components	• Q Guidance System • Mako 3.5 Robotic Arm • Spine Pedicle End Effector (trajectory guidance tube)	• Q Guidance System • Mako 3.5 Robotic Arm • Mako Integrated Cutting System (MICS end effector)
Tools/accessories	• Non-sterile and sterile instruments. • Disposable sterile drape on device.	• Non-sterile and sterile instruments. • Disposable sterile drape on device.
Principle of operation	• Preoperative images • Mako 3.5 Robotic Arm pre-surgery check • Patient Preparation • System Set-up • Image Import (or intraoperative imaging) • Planning • Patient Registration • Mako 3.5 Robotic Arm setup • Navigation including haptic trajectory guidance	• Preoperative images • Preoperative surgical planning and interpretive/intraoperative navigation • Mako 3.5 Robotic Arm pre-surgery check • Patient preparation • System set-up • Image import • Patient registration • Surgical planning • Stereotactic/haptic boundaries during bone preparation and implant placement

- **Technological Comparison between the System 8 Rotary Handpiece and the predicate device**

  There have been no changes to the intended use, design, materials, fundamental scientific technology, or cleaning/ sterilization processes. The only update is to the indications for use for the handpiece reflecting its use as an accessory with Spine Guidance 5.2 Software.

- **Summary of Non-Clinical Testing**

  The subject devices (Spine Guidance 5.2 Software and Mako Spine System) have been evaluated through the following non-clinical performance 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 equivalent to the cited predicate devices.

  - 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.
  - Full system cadaver validation
  - 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).
  - Shelf-life validated per the following standards: ISO 11607-1:2019, ISO 11607-2:2019, ASTM F1980-21.
  - 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.

- **Summary of Clinical Testing**

  No clinical testing was required to support this submission.

- **Conclusion**

  The subject devices, Spine Guidance 5.2 Software, Mako Spine System, and System 8 Rotary Handpiece, perform as intended and are substantially equivalent to the cited predicate devices 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.