DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Leibinger GmbH & Company. KG
Ms. Becky Ditty
Senior Staff Regulatory Affairs Specialist
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

October 31, 2014

Re: K141941
Trade/Device Name: Stryker SpineMap® 3D Navigation System, Stryker SpineMask™ Tracker
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 16, 2014
Received: October 17, 2014

Dear Ms. Ditty:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141941

Device Name
Stryker SpineMap® 3D Navigation System

Indications for Use *(Describe)*
The Stryker SpineMap® 3D Navigation System, when used with a Stryker computer workstation, is intended as a planning and intraoperative guidance system to enable 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. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified.

The Stryker SpineMap® 3D Navigation System assists in precise positioning of instruments for procedures on the spine, including:

• Pedicle screw placement

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141941

Device Name
Stryker SpineMask™ Tracker

Indications for Use *(Describe)*

Indications for Use

The Stryker SpineMask™ Tracker is intended to be used as an accessory to the Stryker SpineMap® 3D Navigation System. It is placed onto the patient's skin dorsal to the spine.

- In combination with intraoperative imaging devices, it enables automatic patient registration for open or percutaneous computer assisted surgery.
- When used for patient tracking, the Stryker SpineMask™ Tracker supports minimally invasive procedures on the lumbar and thoracic spine.

Contraindication

The SpineMask™ Tracker is not intended for use in a MR Environment. The SpineMask™ Tracker is MR unsafe.

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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Navigation

5 510(k) Summary

This chapter provides a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

5.1 Contact Details

Applicant Name:	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany Phone number: +49-761-4512117 Fax number: +49-761-451249117
Registration No.:	8010177
Name of Contact Person:	Becky Ditty Sr. Staff Regulatory Affairs Specialist 4100 E. Milham Ave Kalamazoo, MI 49001 becky.ditty@stryker.com (269) 389-3434
Date Prepared:	October 16, 2014

Table 5-1: Contact Details

5.2 Device Name

Trade Name:	Stryker SpineMap® 3D Navigation System				
Common Name:	Spine Navigation System				
Classification Name:	Product Code	Device	Regulation Number	Class	Review Panel
	Primary Code OLO	Orthopedic Stereotaxic Instrument	21 CFR §882.4560	II	Orthopedic

Table 5-2: Device Name

5.3 Device Description

The Stryker SpineMap® 3D Navigation System is an image guided surgery system to enable open or percutaneous computer-assisted spinal surgery.

The system uses wireless optical tracking technology to display to the surgeon the intraoperative location of navigated surgical instruments relative to a CT image.

The system consists of a software application, smart instruments (e.g. patient/instrument trackers, pointers, navigated surgical instruments), and several accessories to enable the tracking of surgical instruments. The system also includes the SpineMask™ Tracker, a new patient tracking device.

The software application runs on a Stryker computer platform, consisting of a Stryker computer, a navigation camera and an IO-Tablet.

5.4 Intended Use / Indications for Use

Stryker SpineMap® 3D Navigation System Indications for Use

The Stryker SpineMap® 3D Navigation System, when used with a Stryker computer workstation, is intended as a planning and intraoperative guidance system to enable 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. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified.

The Stryker SpineMap® 3D Navigation System assists in precise positioning of instruments for procedures on the spine, including:

- Pedicle screw placement

Stryker SpineMask™ Tracker Indications for Use

The Stryker SpineMask™ Tracker is intended to be used as an accessory to the Stryker SpineMap® 3D Navigation System. It is placed onto the patient's skin dorsal to the spine.

- In combination with intraoperative imaging devices, it enables automatic patient registration for open or percutaneous computer assisted surgery.
- When used for patient tracking, the Stryker SpineMask™ Tracker supports minimally invasive procedures on the lumbar and thoracic spine.

Contraindication

The SpineMask™ Tracker is not intended for use in a MR Environment. The SpineMask™ Tracker is MR unsafe.

5.5 Predicate Devices

The Stryker SpineMap 3D Navigation System, including the SpineMask™ Tracker, has the same intended use and substantially equivalent technological characteristics as the predicate devices shown in the following table:

510(k) Number	K012380	K131214	K022579
Product Code	HAW	HAW	HAW
Trade Name	Stryker Navigation System – Spine & Fluoroscopy Module	Stryker Navigation System – CranialMap Neuro Module	Stryker Navigation System – Knee Module
Manufacturer	Stryker Leibinger GmbH & Co. KG	Stryker Leibinger GmbH & Co. KG	Stryker Leibinger GmbH & Co. KG
Substantial Equivalence Characteristic	Intended Use Technological Features	Intended Use Technological Features	Intended Use

Table 5-3: Legally Marketed Predicate Devices

5.6 Substantial Equivalence Comparison

Table 5-4 provides an overview of the substantial equivalence between the predicate devices and the subject devices.

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Topic	Subject Device	Predicate Devices	Equivalence Assessment
Intended Use			
Indications for use	**Stryker SpineMap® 3D Navigation System Indications for Use** The Stryker SpineMap® 3D Navigation System, when used with a Stryker computer workstation, is intended as a planning and intraoperative guidance system to enable 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. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The Stryker SpineMap® 3D Navigation System assists in precise positioning of instruments for procedures on the spine, including: • Pedicle screw placement **Stryker SpineMask™ Tracker Indications for Use** The Stryker SpineMask™ Tracker is intended to be used as an accessory to the Stryker SpineMap® 3D Navigation System. It is placed onto the patient's skin dorsal to the spine. • In combination with intraoperative imaging devices, it enables automatic patient registration for open or percutaneous computer assisted surgery. • When used for patient tracking, the Stryker SpineMask™ Tracker supports minimally invasive procedures on the lumbar and thoracic spine. **Stryker SpineMask™ Tracker Contraindication** The SpineMask™ Tracker is not intended for use in a MR Environment. The SpineMask™ Tracker is MR unsafe.	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** The Stryker Navigation System is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The system is indicated for any medical condition in which the use of image guided surgery may be appropriate, and where a reference to a rigid anatomical structure such as the skull, or vertebra, can be identified relative to medical images. The Stryker Navigation System – Spine & Fluoroscopy Module supports, but is not limited to, the following surgical procedures: • Pedicle screw placement • Navigation • Precisely positioning instruments such as internal and external fixation devices during orthopedic surgery, to include operations performed with spinal structure, hip and bones. The system is not intended for total joint replacement procedures.	Equivalent

Topic	Subject Device	Predicate Devices	Equivalence Assessment
Indications for use (continued)	See above	**K131214, Stryker Navigation System – CranialMap Neuro Module** The Stryker Navigation System – Cranial Module is intended as a planning and intraoperative guidance system to enable 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. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified. The system should be operated only by trained personnel such as surgeons and clinic staff. The Cranial Navigation system supports, but is not limited to, the following surgical procedures: *ENT Procedures* • Endoscopic Sinus Surgery (ESS) • Intranasal procedures • Ear implant procedures *Neuro Procedures* • Cranial biopsies • Puncture of abscesses • Craniotomies • Craniectomies • Resection of tumors and other lesions • Removal of foreign objects • Skull base procedures • Transnasal neurosurgical procedures • Transphenoidal pituitary surgery • Shunt placement, including pediatric shunt placement • Placement of electrodes for recording, stimulation and lesion generation • Craniofacial procedures • Skull reconstruction procedures • Orbital cavity reconstruction procedures Contraindications • Surgical situation where increasing surgical time may be detrimental to the patient.	Equivalent

Topic	Subject Device	Predicate Devices	Equivalence Assessment
Indications for use (continued)	See above	**K022579, Stryker Navigation System – Knee Module** The Stryker Navigation System – Knee Module is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery. The system is indicated for conditions of the knee joint in which the use of computer assisted surgery may be appropriate. The surgeon has to determine whether the patient's conditions are appropriate for this kind of procedure or not. A pathological condition against the use of this system could be in some cases advanced osteoporosis or a displastic hip.	Equivalent
Main system components	• Computer Platform • SpineMap 3D Software Application • Smart Instruments • Patient Tracker Fixation • Navigated Manual Instruments • Instrument Battery, Trays	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** • Computer Platform • Spine Software Application • Smart Instruments • Patient Tracker Fixation • Navigated Manual Instruments • Instrument Battery, Trays **K131214, Stryker Navigation System – CranialMap Neuro Module** • Computer Platform • CranialMap Neuro Software Application • Smart Instruments • Patient Tracker Fixation • Navigated Manual Instruments • Instrument Battery, Trays	Equivalent

Topic	Subject Device	Predicate Devices	Equivalence Assessment
Main system components (continued)	See above	**K022579, Stryker Navigation System – Knee Module** • Computer Platform • Knee Software Application • Smart Instruments • Patient Tracker Fixation • Navigated Manual Instruments • Instrument Battery, Trays	Equivalent
Modes of operation	• Patient Preparation • System Setup • Image Import • Planning • Patient Registration • Navigation	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** **K131214, Stryker Navigation System – CranialMap Neuro Module** • Patient Preparation • System Setup • Image Import • Planning • Patient Registration • Navigation **K022579, Stryker Navigation System – Knee Module** • Patient Preparation • System Setup • Patient Registration • Navigation	Equivalent

Topic	Subject Device	Predicate Devices	Equivalence Assessment
Localization and tracking technology	• Infrared optical active sensing technology: Infrared light emitted by diodes placed in a known fashion on navigated surgical instruments is sensed by a camera array (navigation camera) on the computer platform, thus allowing for computation of the spatial information	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** **K131214, Stryker Navigation System – CranialMap Neuro Module** **K022579, Stryker Navigation System – Knee Module** • Infrared optical active sensing technology: Infrared light emitted by diodes placed in a known fashion on navigated surgical instruments is sensed by a camera array (navigation camera) on the computer platform, thus allowing for computation of the spatial information	Equivalent
Operating principle	• The software is installed on the computer that is part of the computer platform • Images are imported in DICOM format • The software displays the images and planned items with navigational information on a monitor	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** **K131214, Stryker Navigation System – CranialMap Neuro Module** • The software is installed on the computer that is part of the computer platform • Images are imported in DICOM format • The software displays the images and planned items with navigational information on a monitor **K022579, Stryker Navigation System – Knee Module** • The software is installed on the computer that is part of the computer platform • The software displays the images and planned items with navigational information on a monitor	Equivalent

Topic	Subject Device	Predicate Devices	Equivalence Assessment
Technological Characteristics - SpineMap 3D 3.0 Software			
System accuracy statement	• Mean navigation accuracy of ± 2mm point (tip) displacement and ± 2° angular axis displacement	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** **K131214, Stryker Navigation System – CranialMap Neuro Module** • Mean navigation accuracy of ± 2mm point (tip) displacement and ± 2° angular axis displacement	Equivalent
Supported image modalities	• CT • MRI • PET • 3D C-Arm	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** • CT • MRI • PET • 3D C-Arm **K131214, Stryker Navigation System – CranialMap Neuro Module** • CT • MRI • PET	Equivalent

Topic	Subject Device	Predicate Devices	Equivalence Assessment
Planning features	• Screws • Measurements • Planes • Annotation Points • Trajectories • Segmentations • Anatomical Systems • Correlation • 3D Models • Compositions	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** • Screws • Measurements **K131214, Stryker Navigation System – CranialMap Neuro Module** • Measurements • Annotation Points • Trajectories • Segmentations • Anatomical Systems • Correlation • 3D Models • Compositions	Equivalent
Registration features	• Anatomical Registration • 3D C-arm Registration • Automatic Intraoperative Mask (AIM) Registration	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** • Anatomical Registration • 3D C-arm Registration **K131214, Stryker Navigation System – CranialMap Neuro Module** • Anatomical Registration • Automatic Intraoperative Mask (AIM) Registration	Equivalent

Topic	Subject Device	Predicate Devices	Equivalence Assessment
Technological Characteristics - SpineMask Tracker			
Patient attachment	• Adhesive tape applied to patient's skin	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** • Spine Clamp is attached to patient's spinous process **K131214, Stryker Navigation System – CranialMap Neuro Module** • Adhesive tape applied to patient's skin	Equivalent
Patient tracking	• SpineMask Tracker applied to the dorsal surface of the patient.	**K012380, Stryker Navigation System – Spine & Fluoroscopy Module** • Spine Tracker together with Spine Clamp, with the clamp attached to the spinous process **K131214, Stryker Navigation System – CranialMap Neuro Module** • Patient Tracker together with Mayfield Clamp, with the clamp attached to the patient's skull • Patient Registration Mask Tracker that is applied to the patient's face	Equivalent

Table 5-4: Substantial Equivalence Comparison

The conclusions drawn from the nonclinical tests demonstrate that the Stryker SpineMap® 3D Navigation System performs substantially equivalent to the predicate devices. The differences in the indications for use, technological characteristics and performance characteristics do not raise new questions of safety and effectiveness. Consequently, the Stryker SpineMap® 3D Navigation System is substantially equivalent to the predicate device. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the Stryker SpineMap® 3D Navigation System is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics and performance characteristics.

5.7 Non-Clinical Testing

Validation activities have been conducted to provide assurance that the device meets the performance requirements under its indications for use conditions.

Test	Description
SpineMask Tracker Patient Tracking	Validated the equivalence of SpineMask Tracker and the Spine Clamp / Spine Tracker combination for minimally invasive procedures.
User Needs	Validated the product with users in cadaver labs or simulated use tests. Verified compatibility with conventional operative technique and other devices used in spinal surgery.
Accuracy	Verified the mean navigation accuracy of ± 2mm point displacement and ± 2° angular axis displacement according to ASTM F2554:2010 and in phantom tests. Verified equivalent system accuracy compared to predicate in cadaver tests.
Safety	Verified the effectiveness of all risk controls determined in the device risk analysis.
General Requirements and Performance	Verified all components against their design specifications.
Software	Verification and validation according to IEC 62304:2006 and FDA guidance on general principles of software validation, June 9, 1997.
Shelf Life Testing	Verified functionality of the single-use, sterile device and integrity of the packaging after aging.
Biocompatibility	Verified the biocompatibility of all patient contact materials according to ISO 10993-1:2009 and FDA draft guidance on the use of ISO 10993-1, April 23, 2013.
Electrical Safety	Verified conformance to ANSI/AAMI ES 60601-1:2006-02.
Electromagnetic Compatibility	Verified conformance to IEC 60601-1-2: 2007-03, CISPR 11 Group 1, Class B requirements as well as additional testing to verify compatibility with RFID devices operating in the 125 - 134 kHz frequency band.
Shipping	Verified functionality of the device after simulated shipping conditions.
Sterilization	Validated the EO sterilization process for the single-use, sterile device according to ISO 11135-1:2007 to a sterility assurance level (SAL) of 10-6 and verified that the EO and ECH residuals are within the limits defined in ISO 10993-7:2008.

Table 5-5: Non-clinical Testing

5.8 Clinical Testing

No clinical testing has been conducted.

5.9 Conclusion

The results of the non-clinical tests demonstrate that the Stryker SpineMap® 3D Navigation System performs as safely and effectively as the legally marketed predicate device. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the Stryker SpineMap® 3D Navigation System is substantially equivalent to the predicate devices with respect to its intended use, technological characteristics and performance characteristics.