Stryker Corporation
Andrea Wallen-Gerding
Principal Regulatory Affairs Specialist
Bötzinger Straße 41
Freiburg, D-79111 DE

February 14, 2019

Re: K183196
Trade/Device Name: Stryker Navigation System with SpineMap Go Software Application, Fluoroscopy Trackers and Fluoroscopy Adapters, SpineMask Tracker
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 16, 2018
Received: November 19, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

For
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183196

Device Name
Fluoroscopy Adapters and Fluoroscopy Trackers

Indications for Use *(Describe)*
The Fluoroscopy Adapters and Fluoroscopy Trackers are intended to be used as accessories to the Stryker Navigation System. The Fluoroscopy Tracker is connected to the Fluoroscopy Adapter which is attached to the C-arm fluoroscopy system. The Fluoroscopy Tracker transmits signals that are used by the Stryker Navigation System to calculate the spatial relationship between the C-arm and the patient.

The Fluoroscopy Adapter and Fluoroscopy Tracker may be used as part of the Stryker Navigation System, which 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.

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
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PRAStaff@fda.hhs.gov

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183196

Device Name
Stryker Navigation System with SpineMap Go software application

Indications for Use *(Describe)*
The Stryker Navigation System, when used with the SpineMap Go software application, 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 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, skull, or spine can be identified.

The system assists in the positioning of instruments for procedures on the spine and pelvis, including the following procedures:
- Screw Placement in the spine and pelvis
- Needle Placement in the spine and 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)

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183196

Device Name
SpineMask Tracker

Indications for Use *(Describe)*
The Stryker SpineMask™ Tracker is intended to be used as an accessory to the Stryker Spine Navigation Systems. It is placed onto the patient's skin dorsal to the spine.

- In combination with intraoperative imaging devices, it enables 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.

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.

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

Office Telephone: (269) 389-2884

Fax: (269) 389-5412

Email: andrea.wallengerding@stryker.com

Date Prepared: November 16, 2018

6.3 Device Name

Table 6-1: Device Name

Subject (Modified) Device Information	
Trade/ Proprietary Name	Stryker Navigation System with SpineMap Go software application, SpineMask Tracker, Fluoroscopy Adapters, Fluoroscopy Trackers
Common Name	Spine Navigation System, Fluoroscopy Adapters, Fluoroscopy Trackers, SpineMask Tracker
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 devices included in this Traditional 510(k):

Table 6-2: Predicate Device List

Subject Device	Predicate Device Trade Name	510(k)	Predicate Device Product Code
Stryker Navigation System with the SpineMap Go Software Application	Stryker Navigation System – Spine and Fluoroscopy System with Fluoroscopy 2.3 Software	K012380	HAW
SpineMask Tracker	SpineMask Tracker	K141941	OLO
Fluoroscopy Adapter (Philips BV300, 9")	Fluoroscopy Adapter (Philips BV300, 9")	K012380	HAW

Subject Device	Predicate Device Trade Name	510(k)	Predicate Device Product Code
Fluoroscopy Adapter (OEC 9800, 9")	Fluoroscopy Adapter (OEC 9800, 9")	K012380	HAW
Fluoroscopy Adapter (Ziehm Exposcope, 9")	Fluoroscopy Adapter (Ziehm Exposcope, 9")	K012380	HAW
Fluoroscopy Adapter (Siemens ISO-C, 9")	Fluoroscopy Adapter (Siemens ISO-C, 9")	K012380	HAW
Fluoroscopy Adapter (Philips BV300, 12")	Fluoroscopy Adapter (Philips BV300, 12")	K012380	HAW
Fluoroscopy Adapter (OEC, 12")	Fluoroscopy Adapter (OEC, 12")	K012380	HAW
Fluoroscopy 3D Kit (Siemens ISO-C, 9")	Fluoroscopy 3D kit (Siemens ISO-C, 9")	K012380	HAW
Fluoroscopy 3D Adapter (Siemens ISO-C, 9”)	Fluoroscopy 3D Adapter (Siemens ISO-C, 9”)	K012380	HAW
3D Installation Set (Siemens ISO-C)	3D Installation Set (Siemens ISO-C)	K012380	HAW
Fluoroscopy Tracker Kit, 9"	Fluoroscopy Tracker Kit, 9"	K012380	HAW
Fluoroscopy Tracker Kit, 12"	Fluoroscopy Tracker Kit, 12"	K012380	HAW

6.5 Device Descriptions

6.5.1 Stryker Navigation System with the SpineMap Go™ Software Application Overview

The Stryker Navigation System with the SpineMap Go software application is intended for use as an image guided surgery system to enable open or percutaneous computer assisted spinal surgery. It assists the surgeon in positioning of instrumentation during spinal surgeries. The system provides intraoperative guidance to the surgeon using augmented fluoroscopy. Wireless optical tracking technology is used to estimate the position of navigated surgical instruments and displaying their position on medical fluoroscopic images from mobile C-arm.

The Stryker Navigation System with SpineMap Go software is comprised of a platform, SpineMap Go software, navigated instruments (e.g. patient/instrument trackers, pointers), and accessories. The system uses wireless optical tracking technology to display the intraoperative location of navigated surgical instruments relative to mobile C-arm fluoroscopy images. The platform consists of a computer, camera, monitor and IO (input/output) Tablet. The SpineMap Go software is dedicated for spinal procedures as defined in the Indications for Use. Required navigated instruments include instruments such as a patient tracker, an instrument tracker, and pointers. An instrument battery is also required when a battery powered navigated instrument or calibration device is used.

6.5.1.1 SpineMap Go™ Software Application

The SpineMap Go software application is a required part of the Stryker Navigation System. It is installed by a Stryker representative on the platform. The SpineMap Go software application is used on a platform and interfaces with Stryker navigated instruments and accessories. It is compatible with the

Nav3i Platform family, which includes the NAV3i, NAV3, and NavSuite3.

SpineMap Go is an interactive software application that provides the functions necessary to conduct the indicated spinal procedures. The software application implements methods for image adjustment, image registration, and instrument navigation.

The SpineMap Go Software Application provides new features including the integration of the SpineMask Tracker and the complete Stryker navigation enabled spine instrument portfolio, an updated Image Acquisition component for 2D C-arm support, support for existing C-arm Fluoroscopy Trackers, an updated user interface for improved usability, an updated software architecture, and improved cybersecurity aspects.

6.5.2 SpineMask Tracker

The SpineMask Tracker is a sterile, single use device. It is intended to be used as an accessory to the Stryker Spine Navigation Systems which include the SpineMap 3D and SpineMap Go software applications. (The SpineMask Tracker is currently included as an accessory to the SpineMap 3D 3.1 software application which was cleared per 510(k) K172034.)

The SpineMask Tracker is a flexible, patient tracker that is attached to a patient's skin and provides non-invasive patient tracking of the thoracic and lumbar spine. It is applied to the skin, dorsal to the patient's spine, via an integrated adhesive tape.

The SpineMask Tracker includes infrared LED's that are positioned on the flexible portion of the device. The LED positions are measured by the navigation system after the SpineMask Tracker is applied to the patient's back. Upon activation of the SpineMask Tracker, the LED positions are measured (i.e., captured) by the navigation system. While being tracked, the LED positions are measured and compared to their initial positions as determined during the capturing step. The software is able to detect whether the flexible SpineMask Tracker is deformed when the position of the corresponding LED pairs differ significantly. If this difference is beyond a specific threshold, the LEDs are not used for patient tracking.

6.5.3 Fluoroscopy Trackers and Fluoroscopy Adapters

The Fluoroscopy Trackers and the Fluoroscopy Adapters serve to connect a C-arm with the Stryker navigation system. The Fluoroscopy Adapter is mounted onto the C-arm image intensifier to interface with the Fluoroscopy Tracker. The Fluoroscopy Tracker transmits signals that are received by the navigation camera. The navigation system uses the signals to calculate the spatial relationship between the C-arm and the patient. The position of the C-arm, relative to the patient's anatomy, is displayed on the navigation system monitor.

The radiopaque fluoroscopy markers within the Fluoroscopy Phantom on the tracker are used to correct the image distortion caused by the image intensifier sensor technology and to compute the geometry of the C-arm. The computed geometry of the C-arm is defined by the position of the focal

point relative to the image sensor. The position of the focal point varies based on the C-arm position and gravity deforming the C-arm. The focal point is used later to compute the correct projection of the 3D tool onto the 2D fluoroscopy image.

6.6 Indications for Use

6.6.1 Stryker Navigation System with the SpineMap Go Software Application

The Stryker Navigation System, when used with the SpineMap Go software application, 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 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, skull, or spine can be identified.

The system assists in the positioning of instruments for procedures on the spine and pelvis, including the following procedures:

- Screw Placement in the spine and pelvis
- Needle Placement in the spine and pelvis

6.6.2 SpineMask Tracker

The Stryker SpineMask™ Tracker is intended to be used as an accessory to the Stryker Spine Navigation Systems. 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.

6.6.3 Fluoroscopy Adapters and Fluoroscopy Trackers

The Fluoroscopy Adapters and Fluoroscopy Trackers are intended to be used as accessories to the Stryker Navigation System. The Fluoroscopy Tracker is connected to the Fluoroscopy Adapter which is attached to the C-arm fluoroscopy system. The Fluoroscopy Tracker transmits signals that are used by the Stryker Navigation System to calculate the spatial relationship between the C-arm and the patient.

The Fluoroscopy Adapter and Fluoroscopy Tracker may be used as part of the Stryker Navigation System, which 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.

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 Navigation System with SpineMap Go Software and the Stryker Navigation System – Spine and Fluoroscopy System with Fluoroscopy 2.3 Software

The technological comparison between the subject device, Stryker Navigation System with SpineMap Go software application and the predicate device (Stryker Navigation System – Spine and Fluoroscopy System with Fluoroscopy 2.3 Software) is included in Table 6-3 below. The system accuracy for both the predicate and subject devices are based on non-clinical test data.

Table 6-3: Technological Comparison between Stryker Navigation System with SpineMap Go software application (Subject Device) and the Predicate Device

Item	Subject Device: Stryker Navigation System with SpineMap Go Software Application	Predicate Device: Stryker Navigation System – Spine and Fluoroscopy System with Fluoroscopy 2.3 Software (K012380)
Indications for Use	The Stryker Navigation System, when used with the SpineMap Go software application, 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 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, skull, or spine can be identified. The system assists in the positioning of instruments for procedures on the spine and pelvis, including the following procedures: • Screw Placement in the spine and pelvis • Needle Placement in the spine and pelvis	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 or implants during orthopedic surgery, such as operations performed with spinal structure, hip and bones in the upper and lower extremities and long bones.
Main System Components	• Platform • SpineMap Go Software Application • Navigated Instruments • Accessories	• Platform • Fluoroscopy 2.3 Software Application • Navigated Instruments • Accessories
Modes of Operation	• Patient Preparation • System Set-up • Image Registration • Navigation	• Patient Preparation • System Set-up • Image Registration • Navigation
Localizing and Tracking Technology	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	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	• The software is installed on the computer that is part of the platform

<table>
<tr><th>Item</th><th>Subject Device:
Stryker Navigation System with SpineMap Go Software Application</th><th>Predicate Device:
Stryker Navigation System – Spine and Fluoroscopy System with Fluoroscopy 2.3 Software (K012380)</th></tr>
<tr><td></td><td>• Images are imported in DICOM (Siemens C-arm with proprietary NaviLink 2D protocol) or analog video connection
• The software displays the images with navigational information on a monitor</td><td>• Images are imported in DICOM (Siemens C-arm with proprietary NaviLink 2D protocol) or analog video connection
• The software displays the images and planned items with navigational information on a monitor</td></tr>
<tr><td>System 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.
<table>
<tr><th></th><th>Positional displacement (mm)</th><th>Trajectory Angle Displacement (Degrees)</th></tr>
<tr><td>Median</td><td>0.54</td><td>0.51</td></tr>
<tr><td>Interquartile Range</td><td>0.85</td><td>0.50</td></tr>
<tr><td>99th Percentile</td><td>2.17</td><td>2.09</td></tr>
<tr><td>Mean</td><td>0.68</td><td>0.56</td></tr>
<tr><td>Standard Deviation</td><td>0.59</td><td>0.37</td></tr>
<tr><td>99th Confidence Interval Upper Bound</td><td>2.14</td><td>1.52</td></tr>
</table></td><td>Mean navigation accuracy of ± 2mm point (tip) displacement and ± 2° angular axis displacement.</td></tr>
<tr><td>Supported Imaging Modalities</td><td>• C-arm with image intensifier</td><td>• C-arm with image intensifier</td></tr>
<tr><td>Registration Features</td><td>• Image Registration</td><td>• Image Registration</td></tr>
<tr><td>Energy Source</td><td>• Main Power: Alternating Current (AC) power supply, 100/240 V and 50/60 Hz
• Off-the-Shelf uninterruptable power supply for power interruptions ≤ 6 minutes</td><td>• Main Power: Alternating Current (AC) power supply, 100/240 V and 50/60 Hz
• Off-the-Shelf uninterruptable power supply for power interruptions ≤ 6 minutes</td></tr>
<tr><td>Intended Use Environment</td><td>Operating Room (OR)</td><td>Operating Room (OR)</td></tr>
<tr><td>Input</td><td>Analog Video Input (BNC)
NaviLink2D (Ethernet)</td><td>Analog Video Input (BNC)
NaviLink2D (Ethernet)</td></tr>
<tr><td>Output</td><td>• 2D fluoroscopy image,
• Augmented navigation information
- Instrument
- Screw (3D model)
- Virtual Ruler</td><td>• 2D fluoroscopy image,
• Augmented navigation information
- Instrument
- Screw (Cylinder)
• C-arm position</td></tr>
</table>

Item	Subject Device: Stryker Navigation System with SpineMap Go Software Application	Predicate Device: Stryker Navigation System – Spine and Fluoroscopy System with Fluoroscopy 2.3 Software (K012380)
User Interface	• Black-style graphical user interface • 16:9 screen ratio • One tab per task concept from left to right on top of screen • Image toolbox for navigated tool visualization • Independent image adjustment options for each view • Virtual keyboard • Mouse • IO Tablet with touch screen, USB ports, and CD/DVD drive • Buttons on Navigated Instruments	• Gray-style graphical user interface • 4:3 screen ratio • Movement between task concepts controlled by forward and back arrows. • Current task panel on the right • Image toolbar with image tools • Virtual keyboard • Mouse • IO Tablet with touch screen, USB ports, and CD/DVD drive • Buttons on Navigated Instruments
Camera Working Space	1.25 m (meters)	1.25 m (meters)

6.7.2 Technological Comparison between the SpineMap Go Software and the Fluoroscopy 2.3 Software

The technological comparison between the subject device software (SpineMap Go software) and the predicate device is included in Table 6-4 below. The Fluoroscopy 2.3 software received 510(k) clearance per 510(k) number K012380.

Table 6-4: Technological Comparison between SpineMap Go software (Subject Device) and the Predicate Device Software

Item	Subject Device: SpineMap Go Software	Predicate Device: Fluoroscopy Software 2.3 (K012380)
Computer Operating System	• Windows 8.1 (SPC 3.1)	• Windows XP Embedded (SPC 3.0 - Stryker Personal Computer) • Windows 8.1 (SPC 3.1) • Off-the-Shelf Service Pack 3
Software Version	SpineMap Go 1.0-9/009	Virtual Fluoroscopy 2.3-7/009

6.7.3 Technological Comparison of the SpineMask Tracker, the Fluoroscopy Trackers, and Fluoroscopy Adapter with their Predicate Devices

The design of the SpineMask Tracker and the Fluoroscopy Trackers were updated to meet IEC 60601-1:2012 edition 3.1 and IEC 60601-1-2:2014 4th edition requirements. No changes were made to the design of the Fluoroscopy Adapters. In addition, the Indications for Use statements are being updated for the SpineMask Tracker and the Fluoroscopy Trackers and Fluoroscopy Adapters. The SpineMask Tracker's indications for use statement is being updated to allow it to be used with 2D spine navigation. The indications for use for the Fluoroscopy Trackers and the Fluoroscopy

Adapters is being updated for clarification purposes only. No changes are being made to the performance or risk profile of these devices.

6.8 Summary of Non-Clinical Testing

6.8.1 The function and performance of the subject devices (Stryker Navigation System with SpineMap Go software application, SpineMask Tracker, and Fluoroscopy Trackers and Fluoroscopy Adapters) 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.

6.8.2 Additional testing was performed on the subject devices to ensure the subject devices met their design requirements. A summary of the testing and the results are included in Table 6-5 below.

Table 6-5: Summary of Non-clinical Testing

<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.
<table>
<tr><th></th><th>Positional displacement (mm)</th><th>Trajectory Angle Displacement (Degrees)</th></tr>
<tr><td>Median</td><td>0.54</td><td>0.51</td></tr>
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<tr><td>99th Confidence Interval Upper Bound</td><td>2.14</td><td>1.52</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>Electrical Safety</td><td>Verified conformance to IEC 60601-1:2012 Edition 3.1</td></tr>
<tr><td>Electromagnetic Compatibility</td><td>Verified conformance to IEC 60601-1-2:2014 Edition 4</td></tr>
</table>

6.9 Summary of Clinical Testing

No clinical testing was performed.

6.10 Conclusion

The subject devices, Stryker Navigation System with SpineMap Go software application, SpineMask Tracker, Fluoroscopy Trackers and Fluoroscopy Adapters perform as intended and are substantially equivalent to their respective predicate device with respect to intended use, design, principles of operation, technology, materials, and performance. No new issues of safety or effectiveness have been raised.