October 18, 2017

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

Re: K172034
Trade/Device Name: Stryker Spine Navigation System with SpineMap 3D software application, OrthoLock, nGenius Spine Clamp, Navigated Drill Guide Set, Navigated Xia 3 Awl Tap, Navigated Xia 3 Serrato Tap
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 22, 2017
Received: September 26, 2017

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. 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 (DICE) 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" (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 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 (DICE) 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,

Vincent J. Devlin -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172034

Device Name
Stryker Navigation System with SpineMap® 3D software application

Indications for Use *(Describe)*
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.

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.

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

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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)*
K172034

Device Name
OrthoLock

Indications for Use *(Describe)*
The OrthoLock Anchoring System is intended to be used as an accessory to the Stryker Orthopedic, Trauma, and Spine Navigation Systems. It is a manual instrument intended to be used in surgery to anchor a patient tracker.

The OrthoLock Anchoring System may be used as part of the Stryker Orthopedic, Trauma, and Spine Navigation Systems, which are indicated for any medical condition in which the use computer assisted 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)

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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)*
K172034

Device Name
nGenius Spine Clamp

Indications for Use *(Describe)*
The nGenius Spine Clamp is intended to be used as an accessory to the Stryker Spine Navigation System. The nGenius Spine Clamp is a manual instrument and intended to be used in spine surgery to attach a patient tracker to lumbar or thoracic spinous processes.

The nGenius Spine Clamp may be used as part of the Stryker Spine Navigation, 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)

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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)*
K172034

Device Name
Navigated Drill Guide Set

Indications for Use *(Describe)*
The Navigated Drill Guide Set is intended to be used as an accessory to the Stryker Spine Navigation System. The Navigated Drill Guide Set consists of manual instruments that are intended to be used in spine surgery by providing guidance during drilling.

The Navigated Drill Guide Set may be used as part of the Stryker Spine 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)

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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)*
K172034

Device Name
Navigated Xia 3 Awl Tap

Indications for Use *(Describe)*
The Navigated Xia 3 Awl Taps are intended to be used as accessories to the Stryker Spine Navigation System. They are manual surgical instruments used to facilitate placement of Stryker Spine implants.

The Navigated Xia 3 Awl Taps may be used as part of the Stryker Spine 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.

The Navigated Xia 3 Awl Taps are intended for use with the Rotational Navigation Adaptor and associated trackers to facilitate the placement of screws of the Stryker Spine Xia 3, Xia 4.5, MANTIS, MANTIS Redux, and ES2 Spinal Fixation Systems using the Stryker Spine Navigation System.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172034

Device Name
Navigated Xia 3 Serrato Taps

Indications for Use *(Describe)*
The Navigated Xia 3 Serrato Taps are intended to be used as accessories to the Stryker Spine Navigation System. They are manual surgical instruments used to facilitate placement of Stryker Spine implants.

The Navigated Xia 3 Serrato Taps may be used as part of the Stryker Spine 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.

The Navigated Xia 3 Serrato Taps are intended for exclusive use with the Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Xia 3 System - Serrato using the Stryker Spine Navigation System.

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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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

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Email: andrea.wallengerding@stryker.com

Date Prepared: June 26, 2017

6.3 Device Name

Table 6-1: Device Name

Subject (Modified) Device Information	
Trade/ Proprietary Name	Stryker Navigation System with SpineMap 3D software application, OrthoLock, nGenius Spine Clamp, Navigated Drill guide Set, Navigated Xia 3 Awl Tap, Navigated Xia 3 Serrato Tap
Common Name	Spine Navigation System, Anchoring Device, Navigated Drill Guide, Navigated Drill Guide Calibrator, Navigated Drill Bits, Navigated Drill Bit Stop, Navigated Awl Tap, Navigated Tap
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)	Product Code	Manufacturer
Stryker Navigation System with the SpineMap 3D Software Application	Stryker SpineMap 3D Navigation System	K141941	OLO	Stryker Leibinger GmbH & Co. KG
nGenius Spine Clamp	Percutaneous Spine Clamp	K012380	HAW	Stryker Leibinger GmbH & Co. KG
OrthoLock	OrthoLock	K162341	OLO	Stryker Leibinger GmbH & Co. KG
Navigated Drill Guide	OASYS Adjustable Drill Guide	N/A – Class 1, 510(k) exempt	LXH	Stryker Corporation (Stryker Spine)
Navigated Drill Guide Calibrator	N/A – The Navigated Drill Guide Calibrators are designed specifically for use with the Navigated Drill Guides when they are being calibrated as part of the SpineMap 3D 3.1 software workflow			
Navigated Drill Bits	Predicate for Handle Connection: OASYS Drill Bits	N/A – Class 1, 510(k) exempt	LXH	Stryker Corporation (Stryker Spine)
	Predicate for Cutting Flute Design: Xia CT Drill Bit	N/A – Class 1, 510(k) exempt	LXH	Stryker Corporation (Stryker Spine)
Navigated Drill Bit Stop	Xia 4.5 Refresh Locking Knob	N/A – Class 1, 510(k) exempt	LXH	Stryker Corporation (Stryker Spine)
Navigated Xia 3 Awl Tap	Predicate for Awl Design: Navigated Xia 3 Awl	Letter to File, K012380	OLO	Stryker Corporation (Stryker Spine)
	Predicate for Tap Design: Navigated Xia 3 Taps	Letter to File, K012380	OLO	
Navigated Xia 3 Serrato Taps	Navigated Xia 3 Tap	Letter to File, K012380	OLO	Stryker Corporation (Stryker Spine)

6.5 Device Descriptions

6.5.1 Stryker Navigation System with the SpineMap 3D 3.1 Software Application Overview

The Stryker Navigation System with the SpineMap® 3D 3.1 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 wireless optical tracking technology and displaying the position of navigated surgical instruments relative to medical images such as CT images.

The Stryker Navigation System with SpineMap 3D 3.1 software is comprised of a platform, SpineMap 3D 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 medical images, such as a CT image. The platform consists of a computer, camera, monitor and IO (input/output) Tablet. The SpineMap 3D 3.1 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 also required when a battery powered navigated instrument or calibration device is used.

6.5.2 SpineMap 3D 3.1 Software Application

The SpineMap 3D 3.1 software application is a required part of the Stryker Navigation System. It is installed by a Stryker representative on the platform. The SpineMap 3D 3.1 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 3D 3.1 is an interactive software application that provides the functions necessary to conduct the indicated spinal procedures. The software application implements methods for planning, patient registration, and instrument navigation. It also guides the user through the preoperative and intraoperative workflow process.

The SpineMap 3D 3.1 Software Application provides new features including improved patient registration with non-Hounsfield calibrated imaging devices, updated screw database that includes new Stryker Spine spinal implant screws, an updated Coordinate Engine to improve the visibility of the nGenius Universal Tracker when used on the Rotational Navigation Adapter, implements an Automatic Intraoperative Mask (AIM) Registration fallback workflow to allow the surgeon to identify LEDs when the automatic LED detection for AIM registration fails due to poor image quality or when using non-Hounsfield calibrated systems, implements a new indirect vector calibration workflow to calibrate the new Navigated Drill Guides, and implements new cybersecurity measures.

6.5.3 nGenius Spine Clamps

The nGenius Spine Clamps are manual surgical instruments that are intended to be used in spine surgery to attach a patient tracker to the lumbar or thoracic spinous processes to enable surgical navigation. They are intended to be accessories to the Stryker Spine Navigation System. The nGenius Spine Clamps are available in two different sizes (i.e., short and

long). They can be used in open or percutaneous procedures. The nGenius Spine Clamps are compatible with the nGenius Universal Tracker and the Spine Tracker.

6.5.4 OrthoLock

The OrthoLock is a manual surgical instrument intended to be used to anchor a patient tracker. It is an anchoring system that is used to anchor a patient tracker during computer assisted orthopedic, trauma, and spinal surgeries. It can be used with the Stryker Orthopedic, Trauma, and Spine Navigation Systems.

The OrthoLock anchoring system is intended to be used with the Stryker Navigation Pins and OrthoLock Ex-Pins. It can be tightened or loosened with the screwdriver or Universal Joint Screwdriver.

The OrthoLock Indications for Use are being updated as part of this Traditional 510(k) to allow them to be used during spinal surgical procedures.

6.5.5 Navigated Drill Guide Set

The Navigated Drill Guide Set consists of short and long Navigated Drill Guides, short and long Navigated Drill Guide Calibrators, short and long Navigated Drill Bits, a Navigated Drill Bit Stop, and a Navigated Drill Guide Set Container (class 1 exempt). The instruments of the Navigated Drill Guide Set are intended to be used with the Stryker Navigation System with the SpineMap 3D 3.1 software application.

Descriptions of the instruments that comprise the Navigated Drill Guide Set are included below.

6.5.5.1 Navigated Drill Guides

The Navigated Drill Guides are manual instruments that are intended to provide guidance during drilling. They can be used in open or percutaneous procedures. The Navigated Drill Guides can be used as accessories to the Stryker Spine Navigation System. The Navigated Drill Guides can be navigated using the nGenius Universal Tracker as an instrument tracker.

The Navigated Drill Guides are available in two sizes (i.e., short and long). The Navigated Short Drill Guide is intended for use with the Navigated Short Drill Bits and in spine surgical procedures on the cervical, thoracic, and lumbar spine. The Long Navigated Drill Guide is intended for use with the Long Navigated Drill Bits and in spine surgical procedures on the cervical, thoracic and lumbar spine.

The Navigated Drill Guides can be calibrated using the Navigated Drill Guide Calibrators. Calibration of the Navigated Drill Guides has been incorporated into the SpineMap 3D 3.1 software application workflow. The Navigated Drill Guides can also be

calibrated using the Vector Calibration Device (VCD) or the Point Calibration Device (PCD).

6.5.5.2 Navigated Drill Guide Calibrators

The Navigated Drill Guide Calibrators are manual instruments that are intended to be used to calibrate the Navigated Drill Guides when used with the SpineMap 3D 3.1 software in combination with the Point Calibration Device or Vector Calibration Device. The Navigated Drill Guide Calibrators come in short and long lengths and are intended to be used with the corresponding Navigated Drill Guide. They are not intended to be used for calibrating the Navigated Drill Guides when they are not being used with Navigation.

The Navigated Drill Guide Calibrator cannot be navigated.

6.5.5.3 Navigated Drill Bits

The Navigated Drill Bits are manual instruments that are intended to drill holes of a specified diameter. They drill non-threaded holes. They are designed for use with the Navigated Drill Bit Stop. While the design is based on the Xia CT Drill Bits, they are not designed to be used exclusively with any Stryker Spine Implant System.

The short and long Navigated Drill bits come in a variety of sizes. They must be used with a handle and are designed to be used with Stryker Spine's Short Quick Release Handle (class 1, exempt) and Quick Release Handles (class 1, exempt) which have previously been released to market as Class 1, exempt devices.

The Navigated Drill Bits are single-use only. They will be provided non-sterile, but will need to be sterilized prior to use.

The Navigated Drill Bits cannot be navigated and can be used during non-navigated spine surgical procedures.

6.5.5.4 Navigated Drill Bit Stop

The Navigated Drill Bit Stop is a manual instrument that is intended for use with the short and long Navigated Drill Bits. The Navigated Drill Bit Stop allows the drilling depth of the Navigated Drill Bits to be controlled by pre-setting the drill depth. The Navigated Drill Bit Stop cannot be navigated.

6.5.6 Navigated Xia 3 Awl Taps

The Navigated Xia 3 Awl Taps are manual surgical instruments intended to facilitate placement of Stryker Spine implants. They are a combination of an awl and a tap. The Awl Taps have an awl tip that includes a range of tap diameter sizes with thread designs that are only compatible with bone screws from Stryker Spine's Xia 3, Xia 4.5 (not including Xia Bone CT), ES2, MANTIS, and MANTIS Redux implant systems.

The Navigated Xia 3 Awl Taps are intended as accessories to the Stryker Spine Navigation System. The Awl Taps are designed for use with the Rotational Navigation Adaptor when used for navigated spinal procedures. The Navigated Xia 3 Awl Taps can be used with the Navigated Xia 3 Round Ratchet Handle, Navigated Xia 3 Ratchet T-Handle, and the Navigated Mantis Short Ratchet T-Handle, which have previously received market clearance via letter to file for both navigated and non-navigated spine surgical procedures.

6.5.7 Navigated Xia 3 Serrato Taps

The Serrato Navigated Taps are manual surgical instruments intended to facilitate placement of Stryker Spine's Xia 3 - Serrato screw implants. They have a dual-lead thread geometry and come in a variety of diameter sizes. The thread profile is designed to match that of the Serrato screw implants which is critical in achieving a rigid bone fixation. The Xia 3 Serrato Navigated Taps have a color-anodized titanium ring that corresponds to a specific diameter size for each tap.

The Navigated Xia 3 Serrato Taps are intended as accessories to the Stryker Spine Navigation System. They are designed for use with the Rotational Navigation Adaptor when being used for navigated spinal procedures. The Navigated Xia 3 Serrato Taps are designed to be used with a Modular Handle (Class 1, exempt) if used for non-navigated surgical procedures.

6.6 Indications for Use

6.6.1 Stryker Navigation System with the SpineMap 3D 3.1 Software Application

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.

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.

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

- Screw Placement in the spine, ilium, or pelvis

6.6.2 nGenius Spine Clamps

The nGenius Spine Clamp is intended to be used as an accessory to the Stryker Spine Navigation System. The nGenius Spine Clamp is a manual instrument and intended to be used in spine surgery to attach a patient tracker to lumbar or thoracic spinous processes.

The nGenius Spine Clamp may be used as part of the Stryker Spine Navigation, 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.

6.6.3 OrthoLock

The OrthoLock Anchoring System is intended to be used as an accessory to the Stryker Orthopedic, Trauma, and Spine Navigation Systems. It is a manual instrument intended to be used in surgery to anchor a patient tracker.

The OrthoLock Anchoring System may be used as part of the Stryker Orthopedic, Trauma, and Spine Navigation Systems, which are indicated for any medical condition in which the use computer assisted surgery may be appropriate. The System can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified.

6.6.4 Navigated Drill Guide Set

The Navigated Drill Guide Set is intended to be used as an accessory to the Stryker Spine Navigation System. The Navigated Drill Guide Set consists of manual instruments that are intended to be used in spine surgery by providing guidance during drilling.

The Navigated Drill Guide Set may be used as part of the Stryker Spine 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.

6.6.5 Navigated Xia 3 Awl Taps

The Navigated Xia 3 Awl Taps are intended to be used as accessories to the Stryker Spine Navigation System. They are manual surgical instruments used to facilitate placement of Stryker Spine implants.

The Navigated Xia 3 Awl Taps may be used as part of the Stryker Spine 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.

The Navigated Xia 3 Awl Taps are intended for use with Rotational Navigation Adaptor and associated trackers to facilitate the placement of screws of the Stryker Spine Xia 3, Xia 4.5, MANTIS, MANTIS Redux, and ES2 Spinal Fixation Systems using the Stryker Spine Navigation System.

6.6.6 Navigated Xia 3 Serrato Taps

The Navigated Xia 3 Serrato Taps are intended to be used as accessories to the Stryker Spine Navigation System. They are manual surgical instruments used to facilitate placement of Stryker Spine implants.

The Navigated Xia 3 Serrato Taps may be used as part of the Stryker Spine 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.

The Navigated Xia 3 Serrato Taps are intended for exclusive use with the Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Xia 3 System - Serrato using the Stryker Spine Navigation System.

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 3D 3.1 Software and the Stryker SpineMap 3D Navigation System

The technological comparison between the subject device, Stryker Navigation System with SpineMap 3D 3.1 software application, and the predicate device (Stryker SpineMap 3D Navigation System) is included in Table 6-3 below. The Stryker SpineMap 3D Navigation System received 510(k) clearance per 510(k) number K141941.

Table 6-3: Technological Comparison between Stryker Navigation System with SpineMap 3D 3.1 software application (Subject Device) and the Predicate Device

Item	Subject Device: Stryker Navigation System with SpineMap 3D 3.1 Software Application	Predicate Device: Stryker SpineMap 3D 3.0 Navigation System (141941)
Indications for Use	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. 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. The system assists in the positioning of instruments for procedures on the pelvis and spine, including: • Screw Placement in the spine, ilium, or pelvis	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
Main System Components	• Platform • SpineMap 3D 3.1 Software Application • Navigated Instruments • Accessories	• Platform • SpineMap 3D 3.0 Software Application • Navigated Instruments • Accessories

Item	Subject Device: Stryker Navigation System with SpineMap 3D 3.1 Software Application	Predicate Device: Stryker SpineMap 3D 3.0 Navigation System (141941)
Modes of Operation	• Patient Preparation • System Set-up • Image Import • Planning • Patient Registration • Navigation	• Patient Preparation • System Set-up • Image Import • Planning • Patient Registration • Navigation
Localizing and Tracking 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 • 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
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.	Mean navigation accuracy of ± 2mm point (tip) displacement and ± 2° angular axis displacement
Supported Imaging Modalities	• CT • CTA • MR • MRA • PET	• CT • CTA • MR • MRA • PET
Planning Features	• Screws • Measurements • Planes • Annotation Points • Trajectories • Segmentations • Anatomical Systems • Correlation • 3D Models • Compositions	• Screws • Measurements • Planes • Annotation Points • Trajectories • Segmentations • Anatomical Systems • Correlation • 3D Models • Compositions
Registration Features	• Anatomical Registration • 3D C-Arm Registration	• Anatomical Registration • 3D C-Arm Registration

Item	Subject Device: Stryker Navigation System with SpineMap 3D 3.1 Software Application	Predicate Device: Stryker SpineMap 3D 3.0 Navigation System (141941)
	• Automatic Intraoperative Mask (AIM) Registration which includes the AIM Fallback Workflow	• Automatic Intraoperative Mask (AIM) Registration
Energy Source	• 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	• 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
Intended Use Environment	Operating Room (OR)	Operating Room (OR)
Input	Analog Video Input (AVI)	Analog Video Input (AVI)
Output	• 3D image, • Anatomic orthogonal images, • Analog video image (e.g., endoscopy, target guidance image)	• 3D image, • Anatomic orthogonal images, • Analog video image (e.g., endoscopy, target guidance image)
User Interface	• Monitor with resolution display screen • Virtual keyboard • Mouse • IO Tablet with touch screen, USB ports, and CD/DVD drive • Buttons on Navigated Instruments	• Monitor with resolution display screen • 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 3D 3.1 Software and the Stryker SpineMap 3D 3.0 Software

The technological comparison between the subject device software (SpineMap 3D 3.1 software) and the predicate device (SpineMap 3D 3.0) is included in Table 6-4 below. The SpineMap 3D 3.0 software received 510(k) clearance per 510(k) number K141941.

Table 6-4: Technological Comparison between SpineMap 3D 3.1 software (Subject Device) and the Predicate Device Software

Item	Subject Device: SpineMap 3D 3.1 Software	Predicate Device: SpineMap 3D 3.0 (141941)
Computer Operating System	• Windows XP Embedded (SPC 3.0 - Stryker Personal Computer) • Windows 8.1 (SPC 3.1)	• Windows XP Embedded (SPC 3.0 - Stryker Personal Computer) • Windows 8.1 (SPC 3.1)

Item	Subject Device: SpineMap 3D 3.1 Software	Predicate Device: SpineMap 3D 3.0 (141941)
	• Off-the-Shelf Service Pack 3	• Off-the-Shelf Service Pack 3
Software Version	3.1-8/008	3.0-45/046

6.7.3 Technological Comparison of the Navigated Instruments with their Predicate Devices

The nGenius Spine Clamps are intended to be used to fixate a patient tracker during a navigated spine surgical procedure. The Navigated Drill Guide Set is intended to be used to provide guidance while drilling during a navigated surgical spine procedures. The Navigated Xia 3 Awl Taps are intended to be used to facilitate placement of Stryker Spine spinal implants. The Xia 3 Serrato Taps are intended to be used to facilitate the placement of screws of the Stryker Spine Xia 3 System - Serrato using a Stryker Spine Navigation System.

The nGenius Spine Clamp, Navigated Drill Guide Set, Navigated Xia 3 Awl Tap, and the Navigated Xia 3 Serrato Taps have similar designs to their predicate devices and incorporate the same design features that allow them to be used for navigated spine surgical procedures.

There are no changes to the design of the OrthoLock. The only change is to the Indications for Use for it to allow use with Stryker Spine Navigation Systems.

The modifications to the instruments described in this Traditional 510(k) do not adversely impact the technological characteristics of the predicate devices. A detailed comparison to the predicate devices can be found in Section 13 (Substantial Equivalence) of this Traditional 510(k).

6.8 Summary of Non-Clinical Testing

6.8.1 The function and performance of the subject devices (Stryker Navigation System with SpineMap 3D 3.1 software application, OrthoLock, nGenius Spine Clamps, Navigated Drill Guide Set, Navigated Xia 3 Awl Taps, and Navigated Xia 3 Serrato Taps) 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 the table below.

Item	Summary of Testing
Intended Use/ User Needs	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.

<table>
<tr><th>Item</th><th>Summary of Testing</th></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>99th Percentile</td><td>2.70</td><td>1.07</td></tr>
<tr><td>Mean</td><td>1.07</td><td>0.61</td></tr>
<tr><td>Standard Deviation</td><td>0.50</td><td>0.12</td></tr>
<tr><td>99 % Confidence Interval Upper Bound</td><td>2.26</td><td>0.88</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 10993-1:2009 and FDA draft guidance on the use of ISO 10993-1, June 16, 2016. No new issues of safety or effectiveness were raised.</td></tr>
<tr><td>Electrical Safety</td><td>Verified conformance to ANSI/AAMI ES60601-1:2005/ (R)2012, AND C1:2009 AND A2:2010(R)2012</td></tr>
<tr><td>Electromagnetic Compatibility</td><td>Verified conformance to IEC 60601-1-2: 2007 +AC: 2010, 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.</td></tr>
<tr><td>Shipping</td><td>The functionality of the devices after simulated shipping conditions was verified. No new issues of safety or effectiveness were raised.</td></tr>
<tr><td>Sterilization</td><td>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.</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 3D 3.1 software application, OrthoLock, nGenius Spine Clamps, Navigated Drill Guide Set, Navigated Xia 3 Awl Taps, and Navigated Xia 3 Serrato Taps, 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.