March 23, 2021

Stryker Spine
Megan Callanan
Senior Regulatory Affairs Specialist
600 Hope Parkway SE
Leesburg, Virginia 20175

Re: K203205
Trade/Device Name: Navigated Spine Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 21, 2020
Received: December 23, 2020

Dear Megan Callanan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203205

Device Name
Navigated Spine Instruments

Indications for Use *(Describe)*

Navigated Everest Instruments
The Navigated Everest Screw Inserters and 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 Everest Screw Inserters and 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 Everest Screw Inserters and Taps are intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Everest Spinal Fixation System using the Stryker Spine Navigation System.

Navigated Mesa Instruments
The Navigated Mesa Screw Inserters and 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 Mesa Screw Inserters and 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 Mesa Screw Inserters and Taps are intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Mesa Spinal Fixation System using the Stryker Spine Navigation System.

Navigated Yukon Instruments
The Navigated Yukon Screw Inserters and 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 Yukon Screw Inserters and 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 Yukon Screw Inserters and Taps are intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Yukon Spinal Fixation System using the Stryker Spine Navigation System.

Navigated Xia 4.5- Xia CT Taps
The Navigated Xia 4.5- Xia CT 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 4.5- Xia CT 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 4.5- Xia CT Taps are intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Xia 4.5- Xia CT Spinal Fixation System using the Stryker Spine Navigation System.

Navigated Xia 3- Serrato Deformity Screwdriver
The Navigated Xia 3- Serrato Deformity Screwdriver is intended to be used as an accessory to the Stryker Spine Navigation System. They are manual surgical instruments used to facilitate placement of Stryker Spine implants.

The Navigated Xia 3- Serrato Deformity Screwdriver 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 Deformity Screwdriver is intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine XIA® 3 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K203205

K203205

510(k) Summary: Navigated Spine Instruments	
Submitter:	Stryker Spine 600 Hope Parkway SE Leesburg, VA 20175
Contact Person :	Name: Megan Callanan Phone: (551)262-2429 Email: megan.callanan@stryker.com
Date Prepared:	10/29/2020
Trade Name:	Navigated Spine Instruments
Common Name:	Navigation Instruments
Proposed Class:	Class II
Classification Name:	Orthopedic / Orthopedic Stereotaxic Instruments
Regulation Number	21 CFR 882.4560
Product Code:	OLO
Predicate Devices:	Primary Predicate: K172034 Spine Map 3D 3.1 Additional Predicate: K192911 Brainlab Compatible K2M Navigation Instruments Reference Predicate: K183196 SpineMap Go
Device Description:	Navigated Spine Instruments are nonsterile, reusable surgical instruments (screw inserters and taps) intended to be used when implanting previously cleared components of Mesa, Everest, Yukon, Xia 3, Xia 4.5, and ES2. These instruments are intended to be used with the Stryker Spine Navigation System.
Indications for Use:	**Navigated Everest Instruments** The Navigated Everest Screw Inserters and 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 Everest Screw Inserters and 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 Everest Screw Inserters and Taps are intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Everest Spinal Fixation System using the Stryker Spine Navigation System.

Navigated Mesa Instruments

The Navigated Mesa Screw Inserters and 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 Mesa Screw Inserters and 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 Mesa Screw Inserters and Taps are intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Mesa Spinal Fixation System using the Stryker Spine Navigation System.

Navigated Yukon Instruments

The Navigated Yukon Screw Inserters and 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 Yukon Screw Inserters and 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 Yukon Screw Inserters and Taps are intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Yukon Spinal Fixation System using the Stryker Spine Navigation System.

Navigated Xia 4.5- Xia CT Taps

The Navigated Xia 4.5- Xia CT 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 4.5- Xia CT 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 4.5- Xia CT Taps are intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine Xia 4.5- Xia CT Spinal Fixation System using the Stryker Spine Navigation System. **Navigated Xia 3- Serrato Deformity Screwdriver** The Navigated Xia 3- Serrato Deformity Screwdriver is intended to be used as an accessory to the Stryker Spine Navigation System. They are manual surgical instruments used to facilitate placement of Stryker Spine implants. The Navigated Xia 3- Serrato Deformity Screwdriver 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 Deformity Screwdriver is intended for use with Rotational Navigation Adapter and associated trackers to facilitate the placement of screws of the Stryker Spine XIA® 3 and ES2® Spinal Fixation Systems using the Stryker Spine Navigation System.
Summary of the Technological Characteristics	The subject Navigated Spine Instruments have the same technological characteristics as the predicate device including design, material composition, intended use, function, and range of sizes. Biocompatibility of patient-contacting materials was demonstrated by using well characterized materials that meet applicable standards.
Summary of the Performance Data	Performance testing was conducted to ensure that the Navigated Spine Instruments are acceptable for their intended use, to ensure functionality and compatibility with the Stryker Spine Navigation System using the Rotational Navigation Adapter and associated trackers, and to demonstrate substantial equivalence to the predicate device. The performance of Navigated Spine Instruments has met all acceptance criteria.
Conclusion	Stryker Navigated Spine Instruments are substantially equivalent to the noted predicate device as they have the same intended use, technological characteristics, safety and efficacy profile, and performance specifications. The content of this submission supports the determination of substantial equivalence.