



May 17, 2019

Stryker
Megan Callanan
Regulatory Affairs Associate
2 Pearl Court
Allendale, New Jersey 07401

Re: K183381
Trade/Device Name: Navigation Enabled Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 3, 2019
Received: May 6, 2019

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/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,

for
CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K183381

Device Name
Navigation Enabled Instruments

Indications for Use (Describe)

Stryker Navigation Enabled Instruments are intended to be used in the preparation and placement of Stryker screws (including XIA 3 (including Serrato), XIA 4.5 (including XIA CT), ES2, Mantis, Mantis Redux, and XIA 2) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are specifically designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Stryker Navigation Enabled Screwdrivers are also compatible with the Medtronic IPC POWEREASE 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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510(k) Summary

510(k) Summary: Navigation Enabled	
Submitter:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person:	Name: Megan Callanan Phone: (201)845-4900 Email: megan.callanan1@stryker.com
Date Prepared:	12/04/18
Trade Name:	Navigation Enabled 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: Globus Navigation Instruments (K153203) Additional Predicates: Medtronic Navigated Instruments (K143628, K143375, K140454, K180690)
Device Description:	Navigation Enabled Instruments are nonsterile, reusable instruments, including taps which are operated manually and drivers that can be manually operated or operated with the Medtronic IPC POWEREASE System. These instruments are intended to be used with the Medtronic StealthStation system.
Indications for use:	Stryker Spine Navigation Enabled Instruments are intended to be used in the preparation and placement of Stryker screws (including XIA 3 (including Serrato), XIA 4.5 (including XIA CT), ES2, Mantis, Mantis Redux, and XIA 2) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are specifically designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Stryker Spine Navigation Enabled Screwdrivers are also compatible with the Medtronic IPC POWEREASE System.
Summary of the Technological Characteristics	Navigation Enabled Instruments have the same technological characteristics as the predicate devices including design, material composition, intended use, function, and range of sizes. Biocompatibility of patient-contacting

510(k) Summary: Navigation Enabled	
	materials was demonstrated by using materials that meet applicable standards or are used in 510(k) cleared devices.
Summary of the Performance Data	Design validation testing, including registration, and accuracy, was conducted to ensure the Navigation Enabled Instruments are acceptable for their intended use, to ensure functionality and compatibility with the Medtronic StealthStation® using the NavLock tracker, and to demonstrate substantial equivalence to the predicate instruments. Registration testing was performed to ensure that the instruments can be registered to the StealthStation®. Accuracy testing was completed for comparison to the predicate instruments.
Conclusion	Stryker Spine Navigation Enabled Instruments are substantially equivalent to the noted predicate devices 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.