February 16, 2023

Stryker Corporation
Bryan Hann
Senior Staff Regulatory Affairs Specialist
Boetzinger Strasse 41
Freiburg, Baden-Wuerttemberg D-79111
Germany

Re: K212194
Trade/Device Name: Cranial Guidance Software, Q Guidance System, CranialMask Tracker, EM Stylet, and Navigated Biopsy Needle
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 13, 2023
Received: January 17, 2023

Dear Bryan Hann:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2023.02.16 16:53:33 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212194

Device Name
Cranial Guidance Software

Indications for Use *(Describe)*

The Stryker Q Guidance System, with the Cranial Guidance Software, 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 system assists in the positioning of instruments for cranial procedures, including:

- Cranial biopsies
- Craniotomies
- Craniectomies
- Resection of tumors and other lesions
- Skull base procedures
- Transnasal neurosurgical procedures
- Transphenoidal pituitary surgery
- Craniofacial procedures
- Skull reconstruction procedures
- Orbital cavity reconstruction procedures
- General ventricular catheter and shunt placement
- Pediatric ventricular catheter and shunt placement

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Paperwork Reduction Act (PRA) Staff
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212194

Device Name
Q Guidance System

Indications for Use *(Describe)*

The Q Guidance System is intended as an aid for precisely locating anatomical structures in 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 and where reference to a rigid anatomical structure such as the skull, vertebra, or long bone 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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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K212194

Device Name
CranialMask Tracker

Indications for Use *(Describe)*

The Stryker CranialMask Tracker is intended to be used as an accessory to the CranialMap and the Cranial Guidance software applications. It is intended to be placed on the patient's facial skin and used in combination with preoperative and intraoperative imaging devices to enable automatic patient registration for open or percutaneous computer-assisted surgery. The Stryker CranialMask Tracker can be used as a noninvasive patient tracker to support open or percutaneous cranial neurosurgical procedures.

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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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212194

Device Name
EM Stylet

Indications for Use *(Describe)*

The Stryker EM Stylet is indicated for use as an accessory to the Q Guidance System when used with the Cranial Guidance Software and electromagnetic navigation. It is indicated for use in locating anatomical structures during navigated cranial procedures.

The system is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The system 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 the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

The EM Stylet is indicated for use in the following procedures:
- General ventricular catheter and shunt placement
- Pediatric ventricular catheter and shunt placement

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212194

Device Name
Navigated Biopsy Needle

Indications for Use *(Describe)*

The Stryker Navigated Biopsy Needle is intended to be used as an accessory to the Stryker Q Guidance System when used with the Cranial Guidance Software. It is a side cutting cannula where the cutting action is achieved by rotation of an inner cannula within an outer cannula for use in the stereotaxic biopsy of cranial tissue.

The Stryker Navigated Biopsy Needle may be used as part of the Stryker Cranial Guidance 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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510(k) SUMMARY

A. Device Information

Category	Comments
Sponsor:	Stryker Leibinger GmbH & Co. KG Bötzinger Straße 41 79111 Freiburg, Germany
Correspondent Contact Information:	Bryan K. Hann 1941 Stryker Way Portage, MI 49002 (269) 366-9863
Device Common Name:	Stereotaxic Instruments
Device Regulation & Name:	Regulation: 21 CFR 882.4560
	Name: Neurologic Stereotaxic Instrument
Classification & Product Code:	Classification: Class II
	Product Code: HAW
510(k) Number:	K212194
Device Proprietary Name:	➢ Q Guidance System with Cranial Guidance Software including: • Calibration Body • Passive Optical Pointers • Passive Instrument Trackers • Endoscope Tracker • Instrument Clamps • Patient Tracker Advanced • Precision Targeting System • Universal Base Skull • Elbow 45° • Mayfield Base with Articulating Arm • Electromagnetic Patient Trackers and Tabs • Electromagnetic Pointers • Zeiss Microscope Tracker ➢ Q Guidance System ➢ CranialMask Tracker ➢ EM Stylet ➢ Navigated Biopsy Needle

Predicate Device Information

Predicate Device:	StealthStation S8 Cranial Software v2.0 Stealth Tractography		
	Medtronic StealthStation™ S8 System Platform		
	CranialMask Tracker		
	Stylet, 23 cm		
	MDT Navigable Brain Biopsy Cannula		
Predicate Device Manufacturer:	Medtronic Navigation, Inc.	StealthStation S8 Cranial Software v2.0 Stealth Tractography	
		Medtronic StealthStation™ S8 System Platform	
		Stylet, 23 cm	
	Stryker Leibinger GmbH & Co. KG	CranialMask Tracker	
	IZI Medical Products	MDT Navigable Brain Biopsy Cannula	
Predicate Device Common Name	Stereotaxic Instruments		
Predicate Device Premarket Notification #	StealthStation S8 Cranial Software v2.0 Stealth Tractography		K212397
	Medtronic StealthStation™ S8 System Platform		K162309
	CranialMask Tracker		K162929
	Stylet, 23 cm		K141833
	MDT Navigable Brain Biopsy Cannula		K143241
Predicate Device Classification & Name	Regulation: 21 CFR 882.4560		
	Name: Neurologic Stereotaxic Instrument		
Predicate Device Classification & Product Code	Classification: Class II		
	Product Code: HAW		

B. Date Summary Prepared

February 15, 2023

C. Description of Device

Q Guidance System with Cranial Guidance Software System Overview

The Q Guidance System with Cranial Guidance Software is a computer-assisted stereotaxic, image-guided, planning, and intraoperative guidance system intended to enable open or percutaneous computer-assisted surgery. It assists the surgeon in precisely positioning instruments and locating patient anatomy during cranial surgery.

The Q Guidance System with Cranial Guidance Software system is comprised of a computer platform, Cranial Guidance Software, navigated instruments (e.g., patient/ instrument trackers, pointers), and various system components. The system provides intraoperative guidance to the surgeon using electromagnetic, passive and active wireless optical tracking technologies. The computer platform consists of a computer, camera, electromagnetic field generator and box to plug in electromagnetic instruments, big touchscreen monitor, and a small touchscreen monitor.

The Cranial Guidance Software is dedicated to cranial surgical procedures as defined in the indications for use. Required navigated instruments include instruments such as a patient tracker, an instrument tracker, pointers, suction tubes, seekers, etc. An instrument battery is required when a battery powered instrument or calibration device is used. The Cranial Guidance Software displays the intraoperative location of navigated surgical instruments relative to imported patient medical images via electromagnetic or wireless optical tracking technology. The software provides the functions to perform the indicated navigated cranial surgical procedures. The software guides the user through the necessary preoperative and intraoperative steps required to set-up and perform the navigated cranial surgical procedures.

The Q Guidance System was initially cleared in premarket notification K220593. The only change to this device from its initial clearance is the addition of the electromagnetic tracking technology and the integration of the Zeiss Microscope using the Zeiss Microscope Tracker.

The Cranial Guidance Software includes the following system components described below.

- **System Components**
    - *Passive Optical Navigation Instruments*
        - The Calibration Body is used to validate and calibrate active and passive optically navigated instruments when used with the Cranial Guidance System.
        - The Pointer, Straight and the Registration Pointer are optional system components to the Cranial Guidance Software. They include pins for the connection of reflective spheres that allow them to be tracked by the cranial guidance system.
        - The Instrument Trackers connect to the Instrument Clamps and are optional system components of the Cranial Guidance System.

They enable non-navigated surgical instruments to be tracked by the system. The Elbow, 45° can be used as an interface between the Instrument Trackers and Clamps to allow better visibility with the camera if needed due to patient or procedure setup.

- The Patient Tracker Advanced connects to the Universal Base Skull, which is a patient tracker fixating device, to allow the system to track the patient's head.
- The Endoscope Tracker can be connected to rigid endoscopes to enable tracking by the cranial guidance system.
- The Mayfield Base with Articulating Arm has a mechanical interface to the starburst connection on skull clamps. A Universal Tracker or an nGenius Universal Tracker can be attached to the Mayfield Base with Articulating Arm to enable tracking by the cranial guidance system.
- The Precision Targeting System is comprised of the Precision Targeting Guide, Tracker Sleeve, Needle Sleeve, Twist Drill Sleeve, and the Elite Drill Sleeve. When assembled as intended, the Precision Targeting System provides guidance of the Navigated Biopsy Needle, 3.2 mm Twist Drills, and Stryker's Signature Series of High-Speed Drills with Elite Attachments during drilling and biopsy of cranial tissue.

- *Electromagnetic (EM) Navigation Instruments*
  - The Electromagnetic Pointers are electromagnetically navigated instruments for use in patient registration and locating patient anatomy during navigated cranial neurosurgical procedures when using electromagnetic navigation.
  - The Patient Tracker EM – 10 Uses serves as a patient tracker when using electromagnetic navigation. It is fixed to the patient's skin using a double-sided adhesive pad called Patient Tracker Tab.

- *Zeiss Microscope Tracker*
  - The Zeiss Microscope Tracker can be permanently attached to either a Zeiss Pentero or Kinevo microscope and is used to track the microscope during navigated cranial neurosurgical procedures.

CranialMask Tracker

The CranialMask Tracker is a sterile, single-use, non-invasive, flexible patient tracker. It is indicated as an optional accessory to the Cranial Guidance Software. The CranialMask

Tracker directly attaches to the patient's skin to provide non-invasive tracking of the patient's skull via an integrated tape.

EM Stylet

The EM Stylet is a single use instrument that is only compatible with the Q Guidance System with Cranial Guidance Software. It is used for ventricular catheter and shunt placement in adult and pediatric patients.

Navigated Biopsy Needle

The Navigated Biopsy Needle is currently cleared and marketed by IZI Medical Products for use with the Medtronic StealthStation per 510(k) number K143241. It includes a calibrated biopsy cannula that is used with the Precision Targeting System and the Cranial Guidance Software. It is used in stereotaxic biopsy of cranial tissue. The Navigated Biopsy Needle has the same design as its predicate device. It is a sterile, single-use, device that uses a side-cutting cannula within another cannula to biopsy cranial tissue.

D. Indications for Use

The indications for use for the subject devices are included in the table below.

Subject Device	Indications for Use
Cranial Guidance Software	The Stryker Q Guidance System, with the Cranial Guidance Software, 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 system assists in the positioning of instruments for cranial procedures, including: • Cranial biopsies • Craniotomies • Craniectomies • Resection of tumors and other lesions • Skull base procedures • Transnasal neurosurgical procedures • Transsphenoidal pituitary surgery • Craniofacial procedures • Skull reconstruction procedures • Orbital cavity reconstruction procedures • General ventricular catheter and shunt placement

Subject Device	Indications for Use
	• Pediatric ventricular catheter and shunt placement
Q Guidance System	The Q Guidance System is intended as an aid for precisely locating anatomical structures in 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 and where reference to a rigid anatomical structure such as the skull, vertebra, or long bone can be identified.
CranialMask Tracker	The Stryker CranialMask Tracker is intended to be used as an accessory to the CranialMap and the Cranial Guidance software applications. It is intended to be placed on the patient's facial skin and used in combination with preoperative and intraoperative imaging devices to enable automatic patient registration for open or percutaneous computer-assisted surgery. The Stryker CranialMask Tracker can be used as a noninvasive patient tracker to support open or percutaneous cranial neurosurgical procedures.
EM Stylet	The Stryker EM Stylet is indicated for use as an accessory to the Stryker Q Guidance System when used with the Cranial Guidance Software and electromagnetic navigation. It is indicated for use in locating anatomical structures during navigated cranial procedures. The system is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The system 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 the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. The EM Stylet is indicated for use in the following procedures: • General ventricular catheter and shunt placement • Pediatric ventricular catheter and shunt placement
Navigated Biopsy Needle	The Stryker Navigated Biopsy Needle is intended to be used as an accessory to the Stryker Q Guidance System when used with the Cranial Guidance Software. It is a side cutting cannula where the cutting action is achieved by rotation of an inner cannula within an outer cannula for use in the stereotaxic biopsy of cranial tissue. The Stryker Navigated Biopsy Needle may be used as part of the Stryker Cranial Guidance System, which is

Subject Device	Indications for Use
	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.

*Note: The Q Guidance System was cleared under premarket notification K220593. No changes have been made to the indications for use.

E. Comparison of the Technological Characteristics

A comparison of the technological characteristics of the subject devices included in the scope of this Traditional 510(k) is included below.

- **Stryker Q Guidance with Cranial Guidance Software**

  The technological comparison between the subject device, Stryker Q Guidance System with Cranial Guidance Software, and the predicate device (StealthStation S8 Cranial Software v2.0 Stealth Tractography) is included in the table below. The StealthStation S8 Cranial Software v2.0 Stealth Tractography received 510(k) clearance per 510(k) number K212397.

Characteristic	Application Device: Stryker Q Guidance System with Cranial Guidance Software (K212194)	Predicate Device: StealthStation S8 Cranial Software v2.0 Stealth Tractography (K212397)	Impact on Substantial Equivalence
Company	Stryker Leibinger GmbH & Co. KG.	Medtronic Navigation, Inc.	N/A – No substantial equivalence impact.
Regulation Number	21 CFR 882.4560	21 CFR 882.4560	Identical
Product Code	HAW	HAW	Identical
Intended Use	The Q Guidance System with Cranial Guidance Software is a computer-assisted stereotactic, image-guided, planning, and intraoperative guidance system intended to enable open or percutaneous computer-assisted surgery. It assists the surgeon in precisely positioning instruments and locating patient anatomy during cranial surgery.	The StealthStation™ System, with StealthStation™ Cranial software is designed as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures.	Identical – The intended uses of the subject and predicate devices are the same. Both are used as aids for locating anatomical structures and precisely positioning instruments in either open or percutaneous neurosurgical navigated procedures.
Indications for Use	The Stryker Q Guidance System, with the Cranial Guidance Software, is intended as a planning and intraoperative guidance system	The StealthStation™ System, with StealthStation™ Cranial Software, is intended as an aid for locating anatomical structures in either open or percutaneous	Equivalent - The differences between the subject and predicate devices do not raise

Characteristic	Application Device: Stryker Q Guidance System with Cranial Guidance Software (K212194)	Predicate Device: StealthStation S8 Cranial Software v2.0 Stealth Tractography (K212397)	Impact on Substantial Equivalence
	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 system assists in the positioning of instruments for cranial procedures, including: • Cranial biopsies • Craniotomies • Craniectomies • Resection of tumors and other lesions • Skull base procedures • Transnasal neurosurgical procedures • Transsphenoidal pituitary surgery • Craniofacial procedures • Skull reconstruction procedures • Orbital cavity reconstruction procedures • General ventricular catheter and shunt placement • Pediatric ventricular catheter and shunt placement	neurosurgical procedures. Their use 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 the skull, can be identified relative to images of the anatomy. This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): • Tumor resections • General ventricular catheter placement • Pediatric ventricular catheter placement • Depth electrode, lead, and probe placement • Cranial biopsies	any concerns of safety and effectiveness.
Technology			
System Accuracy Requirement	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.	Under representative worst-case configuration, the StealthStation™ S8 System with StealthStation™ Cranial v2.0 Software, has demonstrated performance in 3D positional accuracy with a mean error ≤	Equivalent – The subject and predicate devices both have a mean accuracy of 2mm for positional accuracy and angular axis displacement

Characteristic	Application Device: Stryker Q Guidance System with Cranial Guidance Software (K212194)	Predicate Device: StealthStation S8 Cranial Software v2.0 Stealth Tractography (K212397)	Impact on Substantial Equivalence
		2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degree.	(trajectory angle) mean accuracy of 2°.
Compatible Optical Instrumentation	Stryker instruments tracked via optical markers or LEDs located on instrument and patient trackers via the optical localizing system.	Medtronic instruments tracked via optical markers or LEDs located on instrument and patient trackers via the optical localizing system.	Equivalent – The subject and predicate devices both utilize optical tracking technology. The compatible instruments used both require the use of optical markers or LEDs located on the navigable instruments and patient trackers.
Compatible EM Instrumentation	Stryker instruments tracked via Electromagnetic (EM) localization technology located within the EM navigated instruments and patient trackers.	Medtronic instruments tracked via Electromagnetic localization technology located within the instrument and patient trackers.	Equivalent – The subject and predicate devices both utilize electromagnetic tracking technology. The compatible instruments require the use of Electromagnetic localization technology located withing the navigable EM instruments and patient trackers.
Software Interface (GUI)	Black-style graphical user interface with a 16:9 screen ratio that includes a Case Dashboard to access all operation modes, an Image box with image tools, a current task panel on the right, and an image settings task panel on the left.	Black and gray style with procedure task overview in left menu option and next/back task flow at bottom of the screen. Software controls for images, planning and instrument management and tractography editing are contained in a right-side bar.	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.
Programming Language	C++, QML	C++ / Java	Equivalent - The differences between the subject and predicate devices do not raise

Characteristic	Application Device: Stryker Q Guidance System with Cranial Guidance Software (K212194)	Predicate Device: StealthStation S8 Cranial Software v2.0 Stealth Tractography (K212397)	Impact on Substantial Equivalence
			any concerns of safety and effectiveness.
Scanner Interface Technology (to imaging devices)	• Network Connectivity • CD • DVD • USB • DICOM Import	• Network Connectivity • CD • DVD • USB • DICOM Import • DICOM Export	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.
Optical Technology	• Manufacturer: Stryker Leibinger • Localizer: FP8000 Camera Note: The FP8000 Camera is component of the Q Guidance System.	• Manufacturer: (Northern Digital Inc.) • Localizer: Vega	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.
Electromagnetic Technology	• Manufacturer: Northern Digital, Inc. • Localizer: Aurora System • Emitter Types: Planar	• Manufacturer: (Medtronic Navigation, Inc.) • Localizer: AxiEM III • Emitter Types: Side, Flat	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.
Computer	Intel-based PC	Intel-based PC	Identical
RFID Reader	Standard RFID receiver running on 13.56 MHz	Capability added to system. Functionality not yet available with this release.	Equivalent – Both the subject and predicate devices feature RFID capability.
Network Connectivity	**Connection Type:** Standard Ethernet; 2.4 gHz and 5.0 gHz Wireless connection	**Connection Type:** Standard Ethernet 2.4gHz and 5.0 gHz Wireless connection	Equivalent – Both the subject and predicate devices utilize Standard Ethernet and have 2.4gHz and 5.0gHz Wireless connection connectivity.

Characteristic	Application Device: Stryker Q Guidance System with Cranial Guidance Software (K212194)	Predicate Device: StealthStation S8 Cranial Software v2.0 Stealth Tractography (K212397)	Impact on Substantial Equivalence
Remote Service Connectivity	Remote secure shell access over high-speed connection with strong public private key authentication and encryption.	Remote service access providing capability for secure remote desktop service over high-speed connection (Branded Remote Presence)	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.
Operating System	Linux-based: Yocto Distro Version 3.1	Linux-based: Ubuntu	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.
Features			
Imagining Modalities	• X-Ray based • MR based • Nuclear medicine based	• X-Ray based • MR based • Nuclear Medicine based	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.
View (Display) Features	• 3D • 3D Targeting • 2D Anatomical (Coronal, Sagittal, Axial) • 2D Anatomical Targeting (Coronal, Sagittal, Axial) • 2D Oriented Targeting (Along 0, Along 90, Perpendicular) • Instrument's Eye (Along 0, Along 90, Perpendicular)	• Ultrasound Video In • Ultrasound Overlay • 3D • 2D Anatomic Orthogonal • Trajectory 1 and 2 • Target Guidance • Trajectory Guidance • Probes Eye • Look Ahead • Microscope Injection • Video Input • Endoscopic	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.

Characteristic	Application Device: Stryker Q Guidance System with Cranial Guidance Software (K212194)	Predicate Device: StealthStation S8 Cranial Software v2.0 Stealth Tractography (K212397)	Impact on Substantial Equivalence
Exam-to-Exam Registration Features	• Same Coordinate System Alignment (Identity Merge Registration) • Manual Alignment (Manual Merge Registration) • Auto Alignment (Automatic Merge Registration)	• Identity Merge Registration • Manual Merge Registration • Automatic Merge Registration	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.
Patient Registration Features	• Point-to-point registration • Surface registration • Mask registration • Automatic intraoperative mask (AIM) registration	• PointMerge™ registration (referred to as Landmark registrations) • Tracer™ registration • Touch registration (previously Touch-N-Go™) • StealthAiR™ registration, O-arm™ registration • Mechanical based registrations (Stereotactic Localizer Registration and StarFix™ Bone Anchor Registration)	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.
Planning Features	• Creation of segments • Planning of approaches • Setting of annotation points • Planning of imported 3D models • Distance and angle measurement • Anatomical alignment of multiplanar images (image merge) • Planning of fiber bundles • Advanced visualization • Automatic segmentation • Semi-automatic head holder removal	• 3D Model Building, including fiber tracts with Standard DTI and Enhanced CSD techniques (fiber bundles) • Plan Entry and Target Selection (planning of approaches) • Advanced Visualization (image settings) • Create Patient Based Anatomical Coordinate Space (none) • Stereotactic Frame Settings (none) • Brain Atlas: Schaltenbrand- Wahren Atlas with Talairach Grid (none) • StarFix™ Designer Annotations (none)	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.

Characteristic	Application Device: Stryker Q Guidance System with Cranial Guidance Software (K212194)	Predicate Device: StealthStation S8 Cranial Software v2.0 Stealth Tractography (K212397)	Impact on Substantial Equivalence
Medical Device Interfaces	**Microscope Navigation:** • Zeiss	**Microscope Navigation:** • Zeiss, Leica **Ultrasound Navigation:** • Aloka and Sonosite Medtronic O-arm® **Stereotactic Frame Systems:** • Fischer ZD, Fischer RM, Integra CRW and Elekta Leksell • Nexframe® Stereotactic System • STarFix™Platform System	Equivalent - The differences between the subject and predicate devices do not raise any concerns of safety and effectiveness.

Technological Comparison of the Navigated Instruments with their Predicate Devices and System Components

The navigated instruments in scope of this Traditional 510(k) have similar designs, materials, intended use, sterilization, and fundamental scientific technology to their predicate devices and system components. The modifications to the instruments do not adversely impact the technological characteristics of the predicate devices. A detailed comparison to the predicate devices and system components can be found in Section 13 (Substantial Equivalence) of this Traditional 510(k).

F. Summary of Supporting Data

The function and performance of the subject devices and system components have been evaluated through non-clinical design verification and validation testing. The results of the evaluation tests demonstrate that the subject devices and system components successfully meet the requirements of their intended use.

G. Discussion of Performance Testing

Performance testing was conducted on the subject devices and system components to ensure they met their design requirements. A summary of the testing and the results are included in the table below.

<table>
<tr><th>Item</th><th>Summary of Testing</th></tr>
<tr><td>Intended Use/ User Needs</td><td>The subject devices and system components 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.

<u>Optical Navigation Accuracy</u>
<table>
<tr><th></th><th>Positional Displacement (mm)</th><th>Trajectory Angle Displacement (degrees)</th></tr>
<tr><td>99% Confidence Interval (Upper)</td><td>2.65</td><td>2.93</td></tr>
<tr><td>Mean</td><td>1.45</td><td>1.38</td></tr>
<tr><td>Standard Deviation</td><td>0.49</td><td>0.62</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Item</th><th>Summary of Testing</th></tr>
<tr><td></td><td>Electromagnetic Navigation Accuracy
<table><tr><th></th><th>Positional Displacement (mm)</th><th>Trajectory Angle Displacement (degrees)</th></tr><tr><td>99% Confidence Interval (Upper)</td><td>2.57</td><td>2.82</td></tr><tr><td>Mean</td><td>1.19</td><td>1.21</td></tr><tr><td>Standard Deviation</td><td>0.54</td><td>0.62</td></tr></table>
Non-clinical accuracy testing for pediatric patients was performed using pediatric models made based on a neonate image set. Accuracy testing for adult patients was performed via a Simulated Use study with cadavers.</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 subject devices and system components against their design specifications. All requirements were met, 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, 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 10993-1:2018 and FDA guidance on the use of ISO 10993-1, September 2020. No new issues of safety or effectiveness were raised.</td></tr>
<tr><td>Electrical Safety</td><td>Verified conformance to IEC 60601-1: 2005, COR. 1:2006, COR. 2:2007, AMD 1:2012 (equivalent to IEC 60601-1:2012 Reprint).</td></tr>
<tr><td>Electromagnetic Compatibility</td><td>Verified conformance to IEC 60601-1-2: 2014, CISPR 11 Group 1, Class A requirements as well as additional testing to verify compatibility with RFID devices operating in the 125 - 134 kHz and 13.56 MHz 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 and system components 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.
The single-use subject device underwent a sterilization validation with Ethylene Oxide to demonstrate that they can be expected to be sterile and have an SAL of 10^{-6} or greater after processing. All</td></tr>
</table>

Item	Summary of Testing
	requirements were met, and no new issues of safety or effectiveness were raised.

H. Summary of Clinical Testing

No clinical testing was performed.

I. Conclusion

The subject devices and system components perform as intended and are substantially equivalent to their respective predicate device intended use, design, principles of operation, technology, materials, and performance.