DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 22, 2017

Stryker Corporation
Brittney Larsen
Staff Regulatory Affairs Specialist
Bötzinger Straße 41
Freiburg Baden-Wurttemberg, D-79111 DE

Re: K162929
Trade/Device Name: Stryker Navigation System With Cranialmap Software Application, Stryker Cranialmap Planning Software Application, Stryker Cranialmask Tracker
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 20, 2017
Received: January 23, 2017

Dear Ms. Larsen:

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 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 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 yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*

K162929

Device Name
Stryker Navigation System with CranialMap software application

Indications for Use *(Describe)*
The Stryker Navigation System, with the CranialMap 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 can be identified.

The system should be operated only by trained personnel such as surgeons and clinic staff.

The system assists in the positioning of instruments for cranial procedures, including:

- Cranial biopsies
- Puncture of abscesses
- Craniotomies
- Craniectomies
- Resection of tumors and other lesions
- Removal of foreign objects
- Skull base procedures
- Transnasal neurosurgical procedures
- Transphenoidal pituitary surgery
- Shunt placement, including pediatric shunt placement
- Placement of electrodes for recording, stimulation and lesion generation
- Endoscopic Sinus Surgery (ESS)
- Intranasal procedures
- Ear implant procedures
- Craniofacial procedures
- Skull reconstruction procedures
- Orbital cavity reconstruction procedures

The user should consult Chapter "System Accuracy" of the safety information to assess if the accuracy of the system is suitable for their needs.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162929

Device Name

Stryker CranialMap Planning software application

Indications for Use *(Describe)*

The Stryker CranialMap Planning software application, when used on a compliant computer, is intended as a planning software to enable open or percutaneous computer-assisted surgery.

The software application is indicated for any medical condition in which the use of computer-assisted planning may be appropriate.

The software application should be operated only by trained personnel such as surgeons and clinic staff.

This can include the following cranial procedures:

- Cranial biopsies
- Puncture of abscesses
- Craniotomies
- Craniectomies
- Resection of tumors and other lesions
- Removal of foreign objects
- Skull base procedures
- Transnasal neurosurgical procedures
- Transphenoidal pituitary surgery
- Shunt placement, including pediatric shunt placement
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- Orbital cavity reconstruction 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162929

Device Name
Stryker CranialMask Tracker

Indications for Use *(Describe)*

The Stryker CranialMask Tracker is intended to be used as an accessory to the Stryker Navigation System, with the CranialMap software application. It is placed onto the patient's face on top of the skin.

- In combination with preoperative and intraoperative imaging devices, it enables 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 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

			Contact Information
510(k) Submitter	Stryker Leibinger GmbH & Co. KG Bötzinger Straße 41 79111 Freiburg, Germany Ph: +1 (269) 389-5293 Fax: +1 (269) 389-5412		
FDA Establishment Registration No.	8010177		
Contact Person	Brittney Larsen MS, RAC Ph: +1 (269) 389-5293 Fax: +1 (269) 389-5412 brittney.larsen@stryker.com		
Date Prepared	October 18, 2016		
			***Subject* Information**
Trade Name	Stryker Navigation System with CranialMap software application; Stryker CranialMap Planning software application; and Stryker CranialMask Tracker.		
Common Name	Stereotaxic instrument		
Classification	II, non-exempt		
Classification Name and Product Code	Neurological Stereotaxic Instrument (21 CFR 882.4560, Product code HAW)		
			Predicate Information
510(k) Number	**Product Code**	**Trade Name**	**Manufacturer**
K131214	HAW	CranialMap Neuro	Stryker Leibinger GmbH & Co. KG
			Reference Information
K141941	OLO	Stryker SpineMask Tracker	Stryker Leibinger GmbH & Co. KG

Device Description

The devices subject to this Traditional 510(k) are within the Stryker Navigation System with CranialMap software application. Subject devices include the CranialMap software application, CranialMap Planning software application, and CranialMask Tracker.

System Overview

The Stryker Navigation System with CranialMap 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 precise positioning of instrumentation during Cranial surgeries. The system provides intraoperative guidance to the surgeon by displaying the position of navigated surgical instruments relative to the medical images.

The Stryker Navigation System with CranialMap software is comprised of a platform, CranialMap software application, navigated instruments, and accessories. The predicate CranialMap Neuro navigation system includes the same parts. The platform consists of a computer, camera, and IO-Tablet (input/output). The CranialMap software is dedicated for the Cranial procedures as defined in the indications for use and identical to the predicate. Required navigated instruments include: a patient tracker; a pointer, suction tube, or seeker; shunt placement tool, and a frameless guide. A battery is the only required accessory of the system, and is used in the navigated instruments only.

CranialMap software application

The CranialMap software application is a required part of the Stryker Navigation System. It is installed by a Stryker representative on the platform. The CranialMap software is used with a Stryker platform and interfaces with Stryker navigated instruments and accessories. The software displays the intraoperative location of navigated surgical instruments relative to imported medical images via wireless optical tracking technology. The subject CranialMap software does not provide direct or indirect patient-contact.

CranialMap is an interactive software application, which provides the functions needed to conduct the indicated cranial procedures. The software application implements the methods for planning, patient registration, and instrument navigation. Furthermore, the software guides the user through preoperative and intraoperative workflow steps. The significant changes made to the subject CranialMap software when compared with the predicate include adding planes and mirroring functionalities and adding compatibility with the CranialMask Tracker.

CranialMap Planning software application

The CranialMap Planning software is an optional accessory to the Stryker Navigation System with CranialMap software application. The CranialMap Planning software application is a standalone software device intended for use on compliant computers as defined in the Safety Information document. It is a new device introduced with this Traditional 510(k).

The subject CranialMap Planning software application is an identical subset of functionality copied from the subject CranialMap software. The planning version serves to preoperatively plan a navigated surgery, outside of the operating room, on a compliant computer. It does not provide registration functionality or surgical navigation guidance,

and it does not interface with instruments or accessories. The preplanned patient record can only be exported to the Stryker Navigation System with CranialMap software. The subject CranialMap Planning software does not provide direct or indirect patient-contact.

CranialMask Tracker
The CranialMask Tracker is a non-invasive patient tracker. It is indicated as an optional accessory to the Stryker Navigation System with CranialMap software application. The subject CranialMask Tracker directly contacts the patient skin, which is identical to the predicate Patient Registration Mask.

The CranialMask Tracker includes a flexible printed circuit board (PCB) mask and closed housing unit. It consists of tracking diodes, green status light emitting diode (LED), communication receiver, battery, an on/off switch, and adhesive backing. The electronic components in the communication unit of the CranialMask Tracker are identical to the components used in the reference device, SpineMask Tracker, cleared by K141941.

This Traditional 510(k) requests clearance for changes made to the CranialMap software used with the Stryker Navigation System. It also seeks clearance for the new CranialMap Planning software and CranialMask Tracker devices as optional accessories to the system.

Indication for Use

Stryker Navigation System with CranialMap software application
The Stryker Navigation System, with the CranialMap 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 can be identified.

The system should be operated only by trained personnel such as surgeons and clinic staff.

The system assists in the positioning of instruments for cranial procedures, including:
- Cranial biopsies
- Puncture of abscesses
- Craniotomies
- Craniectomies
- Resection of tumors and other lesions
- Removal of foreign objects
- Skull base procedures
- Transnasal neurosurgical procedures
- Transphenoidal pituitary surgery
- Shunt placement, including pediatric shunt placement
- Placement of electrodes for recording, stimulation and lesion generation
- Endoscopic Sinus Surgery (ESS)
- Intranasal procedures
- Ear implant procedures
- Craniofacial procedures
- Skull reconstruction procedures

- Orbital cavity reconstruction procedures

The user should consult the Accuracy section of the Safety Instructions to assess if the accuracy of the system is suitable for their needs.

CranialMap Planning software application
The Stryker CranialMap Planning software application, when used on a compliant computer, is intended as a planning software to enable open or percutaneous computer-assisted surgery.

The software application is indicated for any medical condition in which the use of computer-assisted planning may be appropriate.

The software application should be operated only by trained personnel such as surgeons and clinic staff.

This can include the following cranial procedures:
- Cranial biopsies
- Puncture of abscesses
- Craniotomies
- Craniectomies
- Resection of tumors and other lesions
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- Ear implant procedures
- Craniofacial procedures
- Skull reconstruction procedures
- Orbital cavity reconstruction procedures

CranialMask Tracker
The Stryker CranialMask Tracker is intended to be used as an accessory to the Stryker Navigation System, with the CranialMap software application. It is placed onto the patient's face on top of the skin.

- In combination with preoperative and intraoperative imaging devices, it enables 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 procedures.

Technological Characteristic Comparison Summary		
Characteristic	**Predicate Device (K131214)**	**Subject Device**
Type of Use	Prescription use only	No change
Condition for Use	Single-use (battery only) Reusable	No change
Sterility	Sterile (battery only) Non-sterile	No change
Mode/ Mechanism of Action	• Image-guided planning and surgery • Active wireless optical tracking via infrared (IR) LED signal detection by the camera • Instrument tracking relative to patient anatomical images • Spatial computation method	No change
Imaging Modalities	• Computed tomography (CT) • Computed tomography angiography (CTA) • Magnetic resonance (MR) • Magnetic resonance angiography (MRA) • Magnetic resonance imaging (MRI) • Functional magnetic resonance imaging (fMRI), including Diffusion Tensor Imaging (DTI) • Position emission tomography (PET) • Single-photon emission computed tomography (SPECT)	No change
External Power Source	• Alternating current (AC) power supply, 100/240V (Volts) and 50/60Hz (Hertz) • Off-the-shelf (OTS) uninterruptable power supply (UPS) for power interruptions less than or equal to six (6) minutes	No change
Intended user group	Trained clinical staff	No change
Intended use environment	Operating room (OR)	No change
System Accuracy	Mean navigation accuracy of ±2mm and angular axis displacement of $\pm 2^0$	No change
Input	Analog video input (AVI)	No change
Output	3D image, anatomic orthogonal images, endoscopy analog video image, target guidance image, microscope injection	No change
User Interface	• Monitor with high resolution display screen • Virtual keyboard • Mouse	No change

Technological Characteristic Comparison Summary		
Characteristic	**Predicate Device (K131214)**	**Subject Device**
	• IO-Tablet with touch screen, USB ports, and CD/DVD drive • Buttons on navigated instruments	
Camera Working Space	1.25m (meters)	No change
		Software
Computer Operating System	• Windows XP Embedded (SPC 3.0) (Stryker Personal Computer) • Windows 8.1 (SPC3.1) • Off-The-Shelf (OTS) Service Pack 3	No subject change. Windows 8.1 was implemented to maintain the latest technology. This change did not exceed the threshold requiring FDA premarket notification as per 21 CFR 807.81(a)(3). Windows XP and OTS service pack 3 remain identical to the predicate.
Software Version	CranialMap software application Version 2.0	The subject device software version 3.0 was modified, for marketing purposes, in the following manner: 1) addition planes and mirroring functionality, and 2) compatibility with the new CranialMask Tracker. Planes and mirroring offer additional software functionality to users during navigated surgery. The CranialMask Tracker is a new device introduced in this submission and intended as an optional accessory to the Stryker Navigation System with CranialMap software application.
Standalone Software	None	The new CranialMap Planning software is indicated for use with a compliant computer as defined in user documentation. It is identical to the full version CranialMap software, except the registration and navigation features are disabled. It only allows for limited functionality that is within the predicate scope.

Technological Characteristic Comparison Summary		
Characteristic	**Predicate Device (K131214)**	**Subject Device**
Collision Zones	• Segments and annotations can be defined • Collision check option for segments, annotations, and functional overlays during navigation	No change
		Hardware
Microscope Navigation Interfaces	• Zeiss Pentero • Zeiss Pentero 800 • Zeiss Pentero 900 • Leica M525, Leica M530 • Leica M720	No subject change. External, compatible microscope list updated to add more clarity and due to Zeiss portfolio obsolescence. The microscope and navigation system interface remains identical to the predicate. No software changes were made. This change was made since the predicate clearance, however did not require FDA notification as per 21 CFR 807.81(a)(3).
Required System Components	• Platform; • Software application; • Tracker; • Pointer, suction tube, or seeker; • Shunt placement tool; • Frameless guide; and • Battery	No change
		Mask Tracker
Conditions of use	Flexible mask: single-use Communication unit: Reusable	Single-use. Identical to reference device.
Anatomical Location	Patient's face	No change
Battery	Lithium battery	No change
Patient-contacting	Yes	No change
Sterility	Sterile	No change
Sterilization method	Ethylene oxide (EO)	No change
Sterility assurance level	10^{-6}	No change
Sterilization cycle	Number 45	No change

Technological Characteristic Comparison Summary		
Characteristic	**Predicate Device (K131214)**	**Subject Device**
		Performance Data
		Nonclinical

The changes subject to this 510(k) include: software modifications to the CranialMap software, and the introduction of the CranialMap Planning software and CranialMask Tracker. Non-clinical verification and validation testing performed with the subject devices focused on the software changes implemented, and evaluated the visibility and communication, flexibility and adhesion, and working battery time performance of the CranialMask Tracker.

The software changes have been tested in accordance with the Stryker software development life cycle procedure. Verification and validation testing activities were performed at the software system, integration, and component levels to show sufficient implementation of the changes as per the specifications.
Software testing conducted includes:

- System level software verification;
- Accuracy testing;
- Planning software verification with compliant computers; and
- Component level code verification.

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 working space.

The following table summarizes the performance verification results of the system.

	Mean	Standard deviation	99th percentile
Positional displacement	1.11	0.63	2.85
Trajectory angle displacement	1.02	0.51	2.56

In accordance with the design controls process, the following tests were deemed required to evaluate the CranialMask Tracker performance across the hardware and electrical components:

- Communication and visibility;
- Flexibility and adhesion;
- Working battery time;
- Electrical safety;
- Electromagnetic compatibility (EMC);
- Biocompatibility;
- Shelf-life;
- Shipping; and
- Sterilization.

All testing was utilized to verify the subject device performance as intended. The subject CranialMask Tracker testing scheme and methods are identical when compared with the reference device, SpineMask Tracker, cleared under K141941.

Technological Characteristic Comparison Summary		
Characteristic	**Predicate Device (K131214)**	**Subject Device**
The verification and validation testing results demonstrate all requirements were fulfilled. The testing was performed on production equivalent versions of the subject devices. The testing was relevant and the results met the pre-defined acceptance criteria. The testing results confirm the changes and new devices meet the pre-defined specifications and do not raise different questions of safety and effectiveness for the subject devices.		
Clinical		
Clinical testing was deemed not required to support the safety and effectiveness of the subject devices for the intended use.		
Conclusion		
The intended use, basic design, and fundamental scientific technology are identical between the subject and predicate devices. The subject changes add planes and mirroring functionality and compatibility with the CranialMask Tracker. The CranialMap Planning software and CranialMask Tracker are introduced in this submission. Verification and validation testing results confirm there are no different questions of safety or effectiveness. The changes do not constitute a new intended use, and do not affect the control mechanism, operating principle, or energy type. The information presented in this notification supports the subject devices to be as safe and effective as the predicate, and therefore supports a determination of substantial equivalence.		