K131214

stryker

Navigation

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

Applicant Name:	Stryker Leibinger GmbH & Co. KG - Navigation Boetzinger Strasse 41 D-79111 Freiburg, Germany Phone number: +49-761-4512 117 Fax number: +49-761-4512 49117
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Date prepared:	12 September 2013

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2. Device Name

Trade Name:	CranialMap Neuro
Common Name:	Navigation software for cranial surgeries
Classification Name:	

Product Code	Device	Regulation Number	Class	Review Panel
Primary Code: HAW	Neurologic stereotaxic instrument	21 CFR §882.4560	II	Neurology

3. Legally Marketed Predicate Device

The legally marketed predicate device is the Cranial Module as cleared in K062640 Stryker Navigation System – Cranial Module.

510(k) Number	Product Code	Trade Name	Manufacturer
K062640	HAW	iNtellect Cranial iNtellect ENT	Stryker Leibinger GmbH & Co. KG - Navigation Boetzinger Strasse 41 D-79111 Freiburg, Germany

4. Device Description

The Stryker Navigation System – CranialMap Neuro Module 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 CranialMap Neuro Module is the Stryker Navigation System for cranial surgeries as described in the indications for use statement.

The subject device is the Stryker Navigation Application Software – CranialMap Neuro which together with the Stryker Navigation Platform, Smart Instruments and Accessories forms the Stryker Navigation System – CranialMap Module. It is therefore regarded as a component of the Stryker Navigation System – CranialMap Neuro Module. The design modifications introduced with the Stryker Navigation Application Software CranialMap Neuro are intended to increase the user comfort, to enhance the look and feel of the software and to simplify and extend the provided functions using the latest system platform technology.

5. Indications for use

The Stryker Navigation System - CranialMap Neuro Module is a navigation surgical software module that, when used with a specific 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 system should be operated only by trained personnel such as surgeons and clinic staff. The CranialMap Neuro Navigation system supports, but is not limited to, the following surgical 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
- 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

6. Substantial Equivalence Comparison

In summary, the indications for use of the modified Stryker CranialMap Neuro Module are identical to the predicate device Cranial Module. Furthermore, the technological characteristics of the modified CranialMap Neuro Application Software are substantially equivalent to the original Cranial Application Software. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the CranialMap Neuro Module is substantially equivalent to the predicate device.

The following table gives an overview of the substantial equivalence reflecting all modifications being made between the predicate device and the subject device.

Topic	**Predicate Device** iNtellect Cranial Software	**Subject Device** CranialMap Neuro Software	**Equivalence assessment**
Indications for Use	Refer to chapter 5 "Indications for use"	Refer to chapter 5 "Indications for use"	**Identical** Identical, except for the module name, titles and the order of listed indications for use.
Look of the Software User Interface	Grey-style graphical user interface on 4:3 screen ratio, one tab per task concept from left to right on top of screen, image box with image tools and task panel on the right	Black-style graphical user interface on 16:9 screen ratio, one tab per task concept from left to right on top of screen, image box with image tools and task tablet on the right	**Equivalent** Refreshed and touch-enabled graphical user interface on HD screen. Changes are minor and do not alter the way the software performs nor affect safety and effectiveness of device.
Modes of Operation	Software workflow controlled by tabs from left to right, registration planning tab after planning tab.	Software workflow controlled by tabs from left to right, registration planning tab moved before planning tab.	**Equivalent** Modification improves the ease of use of the software and does not negatively affect the safety and effectiveness of the proposed device.

Topic	**Predicate Device** iNtellect Cranial Software	**Subject Device** CranialMap Neuro Software	**Equivalence assessment**
Control Mechanism	• Mouse • Keyboard • Buttons on navigated sterile smart tools.	• Mouse • Virtual Keyboard • Buttons on navigated sterile smart tools. • IO-Tablet with touch screen	**Equivalent** The control mechanism during surgery is identical. The control mechanism before surgery is equivalent: mouse, keyboard and touch screen.
Operating Principle	The iNtellect Cranial software is installed on the computer that is part of the Navigation system platform. Images are imported in DICOM format.	The CranialMap software is installed on the computer that is part of the Navigation system platform. Images are imported in DICOM format.	**Identical** The operating principle on the Stryker Platform is unchanged.
Accuracy Statement	Within the camera working space, the system has a mean accuracy of 2 mm for translation and 2° for rotation.	Within the camera working space, the system has a mean accuracy of 2 mm for translation and 2° for rotation.	**Identical**
Registration Accuracy	The root mean square value is displayed as mean error of the registration.	The root mean square value is displayed as mean error of the registration.	**Identical**
Check for Sustained Accuracy Intra-operatively	Navigation instrument's tip geometry check on initialization of instrument. Intra-operative interactive landmark checks demanded by the software, e.g. during mandatory registration confirmation step.	Navigation instrument's tip geometry check on initialization of instrument. Intra-operative interactive landmark checks demanded by the software, e.g. during mandatory registration confirmation step.	**Identical** An additional video guidance how to check the instrument's tip geometry makes the device more users friendly and does not negatively affect the safety and effectiveness of the proposed device.

Topic	Predicate Device iNtellect Cranial Software	Subject Device CranialMap Neuro Software	Equivalence assessment
System Components			
Localization Technology and Working Sphere	Infrared optical active sensing technology: Infrared light emitted by diodes placed in a known fashion on instruments (trackers) is sensed by a camera array thus allowing for computation of the spatial information.	Infrared optical active sensing technology: Infrared light emitted by diodes placed in a known fashion on instruments (trackers) is sensed by a camera array thus allowing for computation of the spatial information.	**Identical** The Navigation Camera is the same camera as used for the predicate device.
Navigation System Platform	Stryker Navigation System II – Cart , Stryker eNlite: • Stryker Navigation Camera • Mouse, Keyboard • Stryker PC Computer	Stryker Navigation Platform: • Stryker Navigation Camera • IO-Tablet • Stryker PC-3 Computer	**Equivalent** The same navigation camera and equivalent PC based components are used. The IO-tablet interface to control the application is a state-of-the-art alternative to using a mouse and keyboard for user's convenience.
OR Display	Display properties: • 4:3 LCD monitor • 1280 x 1024 pixel resolution • 19" screen	Display properties: • 16:9 LCD monitor • 1980 x 1080 pixel resolution • 32" screen	**Equivalent** The larger high resolution display does not negatively affect the safety and effectiveness of the subject device.
Smart Instrument Technology (Trackers)	Active, battery powered, wireless instrumentation with bi-directional IR-communication and IR-LEDs for tracking	Active, battery powered, wireless instrumentation with bi-directional IR-communication and IR-LEDs for tracking	**Identical** All smart instruments supported by the predicate device are supported by the subject device as well.

Topic	**Predicate Device** iNtellect Cranial Software	**Subject Device** CranialMap Neuro Software	**Equivalence assessment**
Calibration of Instrument Dimensions	Workflow to calibrate and validate the navigated instruments during the operation.	Workflow to calibrate and validate the navigated instruments during the operation.	**Identical**
Disposable Parts	Batteries for trackers, registration markers, Frameless Guide, Patient Registration and tracking mask.	Batteries for trackers, registration markers, Frameless Guide, Patient Registration and tracking mask.	**Identical**
Interfaces			
Scanner Interface Technology (to imaging devices)	Magneto Optical Disk CD, DVD, USB Network connectivity DICOM storage client	CD, DVD, USB Network connectivity DICOM storage client DICOM query/retrieve	**Equivalent** Modification to support state-of-the-art scanner interfaces.
Supported imaging modalities	CT, CTA MR, MRA, fMRI PET, SPECT	CT, CTA MR, MRA, fMRI PET, SPECT	**Equivalent** More convenient image modality correlation based on DICOM frame-of-reference ID supported.
Microscope interfaces	Zeiss NC4, Zeiss Pentero, Leica M5xx, Leica M720 microscope models	Zeiss NC4, Zeiss Pentero, Zeiss Pentero 900, Leica M5xx Leica M720 microscope models	**Equivalent** The additional support of the Zeiss Pentero 900 microscope is identical to the Pentero microscope except for a new microscope ID.

Topic	**Predicate Device** iNtellect Cranial Software	**Subject Device** CranialMap Neuro Software	**Equivalence assessment**
Operating System and Implementation Technology			
Platform Operating System	Windows 2000 Windows XP	Windows XP	**Equivalent** Higher version of Windows operating system used.
Software Implementation	C and C++ programming applying object oriented analysis and design methods, Qt GUI design and up-to-date continuous integration and testing tools in a Microsoft development environment.	C and C++ programming applying object oriented analysis and design methods, Qt GUI design and up-to-date continuous integration and testing tools in a Microsoft development environment.	**Equivalent** Additional methods have been applied to the software development of the subject device for state-of-the-art software quality, e.g. code coverage measurements and 100% code reviews.
Use of Off-the-Shelf (OTS) Software	OTS software for logging, visualization, algorithms, 3D graphics, multi-threading, GUI components, volume rendering, multi-modality matching, backup on CD and cpp-templates.	OTS software for logging, visualization, algorithms, 3D graphics, multi-threading, GUI components, volume rendering, multi-modality matching, backup on CD and cpp-templates. DICOM Tool Kit	**Equivalent** For the CranialMap Neuro Software the same Off-the-Shelf software components that have already been used for the predicate device are used with updated versions where appropriate. The new DICOM Query/Retrieve extension is based on the DICOM Tool Kit.

Topic	Predicate Device iNtellect Cranial Software	Subject Device CranialMap Neuro Software	Equivalence assessment
CranialMap Neuro Modifications			
Touch Screen Functionality	• No touch screen • GUI operated via Mouse input	• Touch on IO-tablet can be used alternatively to mouse control	**Equivalent** Additional touch screen functionality does not negatively affect the safety and effectiveness
LiveCam System Setup	• System setup using side and top view of working sphere.	• System setup using side and top view of working sphere. • Additionally a "localizer's eye" live video view option.	**Equivalent** The additional option using the LiveCam does not affect the performance or the indications for use of the subject device.
Collision Zones	• Segments and annotations can be defined	• Segments and annotations can be defined • Collision check option for segments, annotations and functional overlays during navigation	**Equivalent** An additional option for audible and visual feedback during navigation is provided. This modification does not negatively affect safety and effectiveness or change the indications for use of the subject device.

Topic	**Predicate Device** iNtellect Cranial Software	**Subject Device** CranialMap Neuro Software	**Equivalence assessment**
Image series import and handling	• Anatomical and functional MRI data is imported as separate image series. • The "identity correlation" feature is used to correlate functional data to the appropriate anatomical MRI series. • The correctness of the image correlation must be confirmed during image import.	• Functional MRI images are detected during image import as overlays of a related anatomical MRI image series automatically. • System applies an "identity correlation" based on DICOM reference frame ID. • The correctness of the image correlation must be confirmed during image import. • Deletion of imported image series.	**Equivalent** Simplification by reducing number of steps needed to correlate image modalities. Like in the predicate device the user must confirm the result. For convenience an unintentionally imported image series can be removed. The modification does not negatively affect the safety and effectiveness of the subject device.
3D model visualization	• Advanced virtual surgical planning based on 3D DICOM data, e.g. a CT scanned implant possible.	• Planning based on 3D model data, e.g. STL models is possible. The 3D models can be loaded and aligned with anatomical image data.	**Equivalent** Advanced virtual planning is enhanced but no change of indications for use. Change does not negatively affect safety and effectiveness.

Topic	Predicate Device iNtellect Cranial Software	Subject Device CranialMap Neuro Software	Equivalence assessment
Automatic intra-operative mask (AIM) registration	• Automatic mask registration and tracking based on skin surface extraction.	• Automatic mask registration and tracking based on skin surface extraction. • The mask is attached on the patient during the CT scan and AIM registration is able to detect the LED positions of the mask in the scan.	**Equivalent** Additional mask registration method using a CT scan while the mask is attached to the patient. The established point-to-point registration algorithms are used. No change of the indications for use. Change does not negatively affect safety and effectiveness.

7. Non-clinical Testing

Validation activities, including human factors validation testing, have been conducted to provide assurance that the device meets the performance requirements under its indications for use conditions. In addition, system software validation acc. to IEC 62304 "Medical device software - Software life cycle processes", have been performed to show that the device is safe and effective.

8. Clinical Testing

No clinical testing has been conducted.

9. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the Stryker Navigation Application Software CranialMap Neuro performs as safely and effectively as the legally marketed device identified in chapter 3. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the Stryker Navigation System – CranialMap Neuro Module is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 18, 2013

Stryker Corporate
Ms. Lilian Eckert
Boetzinger Str. 41
Freiburg, Baden-Wuerttemberg, GM 79111

Re: K131214
Trade/Device Name: Cranial Map Neuro Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: September 12, 2013
Received: September 16, 2013

Dear Ms. Eckert:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131214

Device Name: Stryker CranialMap Neuro Module

Indications For Use:

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- Endoscopic Sinus Surgery (ESS)
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- Craniofacial procedures
- Skull reconstruction procedures
- Orbital cavity reconstruction procedures

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S