DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 8, 2015

Stryker Leibinger GmbH & Co. KG
Robin Rowe
Director, Regulatory/Clinical Affairs
Boetzinger Strasse 41
Freiburg, Baden-Wuerttemberg D-79111 Germany

Re: K150301
Trade/Device Name: NavSuite3 Kit
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, OLO
Dated: June 5, 2015
Received: June 8, 2015

Dear Ms. Rowe:

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" (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 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,

Carlos L. Pena -S

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)*
K150301

Device Name
NavSuite®3 Kit

Indications for Use *(Describe)*

The NavSuite®3 Kit is a computer workstation that, when used with CranialMap Neuro Navigation software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient. The clinical setting and target population for the NavSuite®3 Kit is that of a patient undergoing a cranial surgical procedure using stereotactic techniques.

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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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)*
K150301

Device Name
NavSuite®3 Kit

Indications for Use *(Describe)*

The NavSuite®3 Kit is a computer workstation that, when used with SpineMap 3D Navigation software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient. The clinical setting and target population for the NavSuite®3 Kit is that of a patient undergoing an orthopaedic spinal surgical procedure using stereotactic techniques.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the NavSuite®3 Kit is provided below.

Device Common Name:	Neurological Stereotaxic Instrument
Device Proprietary Name:	NavSuite®3 Kit
Applicant:	Stryker Leibinger GmbH & Co. KG – Navigation Boetzinger Strasse 41 D-79111 Freiburg, Baden-Wuerttemberg, Germany
Contact:	Robin L. Rowe, MS, RAC Director, Regulatory/Clinical Affairs Stryker Corporation 4100 E. Milham Ave. Kalamazoo MI 49001 Phone: 269.389.3893 Cell: 269.806.5779 Fax: 269-389-2375
Date Prepared:	June 5, 2015
Classification Regulation:	Stereotaxic Instrument, 21 CFR 882.4560, Class II
Panel:	Neurology
Primary Product Code:	HAW - Neurological Stereotaxic Instrument
Secondary Product Code:	OLO – Orthopedic Stereotaxic Instrument
Predicate Device:	Stryker NAV3i Platform (K130874)

Indication for Use:

The NavSuite®3 Kit is a computer workstation that, when used with CranialMap Neuro Navigation software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient. The clinical setting and target population for the NavSuite®3 Kit is that of a patient undergoing a cranial surgical procedure using stereotactic techniques.

The NavSuite®3 Kit is a computer workstation that, when used with SpineMap 3D Navigation software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient. The clinical setting and target population for the NavSuite®3 Kit is that of a patient undergoing an orthopaedic spinal surgical procedure using stereotactic techniques.

Device Description:

The Stryker Navigation System is a planning and intraoperative guidance system which assists in various surgical procedures. It allows for the localization of surgical instruments and visualization of their position relative to patient specific images and/or patient specific anatomical landmark information assisting the surgeon in performing the intervention at a high level of precision. For localization, active optical tracking based on infrared light is used. Using three linear sensors, the Navigation Camera detects signals from infrared light emitting diodes which are attached to the instruments to be localized. The Computer Monitor displays the navigation information to the user.

The NavSuite®3 Kit is a minor modification of the previously cleared Stryker NAV3i Platform. The NavSuite®3 Kit consists of the same main components that were cleared as the NAV3i Platform in K130874. The NAV3i Platform (K130874) consisted of a mobile cart, a computer system, a monitor, an IO Tablet and a navigation camera. The subject of this Special 510(k) is that the system is now modified to provide these same components, without the mobile cart and without the monitor. The computer, IO Tablet and navigation camera are now provided as separate components that can be configured and affixed in the operation room suite based on user preferences. The monitor that was provided with the NAV3i Platform is not provided with the NavSuite®3 Kit. The NavSuite®3 Kit is compatible with any monitor that meets the specifications provided in the Instructions for Use.

Like the predicate Nav3i platform, the NavSuite3 Kit platform is compatible with the following previously cleared Stryker Software Application Modules:

- K131214 CranialMap Neuro Navigation (Including CranialMap Express)
- K141941 SpineMap Navigation

Performance Data:

A functional risk analysis for the NavSuite®3 Kit was conducted and applied in accordance with ISO 14971, 2nd Edition: Medical Devices – Application of Risk Management to Medical Devices (2007).

The results of the risk analysis for the NavSuite®3 Kit determined that the device modifications which are the subject of this 510(k) do not introduce any new risks compared to the predicate device. All existing risks that were identified for the predicate device are the same for the subject device and are mitigated to a risk level as low as reasonably possible. The effectiveness of all mitigation measures is verified per the testing detailed in Table 1.

Table 1: Summary of Performance Testing

Modification	Description	Tests Performed
Cart with Castors	Cart is not used in the NavSuite®3 Kit.	No testing required.
UPS	No UPS is included in NavSuite®3 Kit	System test: Shutdown and crash behavior was tested with Navigation Software Application Modules integration tests

Modification	Description	Tests Performed
Operating System	Same as the NAV3i OS, with minor configuration changes.	Component test: To show that the configurations are implemented and effective System test: To show that fixed resolution was used on several monitors
Monitor	No monitor is provided with NavSuite®3 Kit. Any compatible monitor that meets the specifications provided in the Instructions for Use can be used.	System test: Various compatible monitors were tested with native resolution of 1920 x 1080 pixels, divided on the Navigation Software Application Modules integration tests
Navigation Camera Mounting	Camera will be fixed on ceiling-mounted arm using an adapted camera joint.	System test: Automated mechanical stress tests to show reliability by simulated intraoperative use over lifetime, rotational and vertical adjustment and that the camera joint can be moved without restrictions within the range of motion, using statistical methods A lifetime of 1000 movement cycles was estimated for a camera joint. This resulted in tests with five test samples of camera joints, each over 5687 test cycles.
Navigation Camera Cables	Additional Navigation camera data and power cables are needed. Navigation camera data cables include optical fibers. Camera will be fixed on ceiling-mounted arms	Component Test: To verify voltage and data transfer. System Tests: Automated mechanical stress tests to show reliability of the Navigation camera cables by simulated intraoperative use over specified lifetime using statistical methods For a camera cable set (power and data), a lifetime of 1000 movement cycles was estimated. This resulted in tests with five test samples of camera cable sets (power and data), each over 5687 test cycles.
LiveCAM	Not provided with NavSuite®3 Kit	System test: Verify that applicable Software Application Module is not affected. Tested with Navigation Software Application Module integration test.

Substantial Equivalence:

Table 2 provides a comparison of the technological characteristics of the subject device to the predicate device and an assessment of the equivalence of each characteristic.

Table 2: Device Comparison Table

	Proposed Device	Predicate Device	Equivalence Assessment
Device Name	NavSuite®3 Kit	NAV3i Platform	N/A
510(k) Number	TBD	K130874	N/A
Submitter	Stryker Corporate	Stryker Corporate	Identical
Classification Regulation	882.4560	882.4560	Identical
Product Code	HAW, OLO	HAW, OLO	Identical
Indication	The NavSuite®3 Kit is a computer workstation that, when used with CranialMap Neuro Navigation software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient. The clinical setting and target population for the NavSuite®3 Kit is that of a patient undergoing a cranial surgical procedure using stereotactic techniques. The NavSuite®3 Kit is a computer workstation that, when used with SpineMap 3D Navigation software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient. The clinical setting and target population for the NavSuite®3 Kit is that of a patient undergoing an orthopaedic spinal surgical procedure using stereotactic techniques.	The NAV3i is a computer workstation that, when used with specific Stryker Navigation surgical software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient. The clinical setting and target population for the NAV3i is that of a patient undergoing a surgical procedure using stereotactic techniques.	Identical
Contraindication	The NavSuite®3 Kit is not intended for use in an MR environment. The NavSuite®3 Kit is MR unsafe.	The NAV3i Platform is not intended for use in a MRI environment. The NAV3i Platform is MR unsafe.	Identical

	Proposed Device	Predicate Device	Equivalence Assessment
Power Supply	External power source: AC Power supply, 100/240V, 50/60Hz. No UPS provided.	External power source: AC Power supply, 100/240V, 50/60Hz. The system is equipped with an off-the-shelf uninterruptible power supply (UPS) for power interruptions less than or equal to 6 minutes.	**Equivalent:** The subject device and predicate device use the same power supply. The UPS is not needed for the subject device based on it being a fixed installation of the components.
Computer	Windows XP, Intel I5 Platform with WLAN capability	Windows XP, Intel I5 Platform with WLAN capability	Identical
IO-Tablet and RFID Reader	Touch screen tablet with USB ports and CD/DVD drive and RFID Reader	Touch screen tablet with USB ports and CD/DVD drive and RFID Reader	Identical
Monitor Arm	Not provided.	Weight balanced articulated arm, swing range of 300°	**Equivalent:** The monitor arm is not needed for the subject device because a monitor is not provided.
Monitor	The NavSuite®3 Kit is compatible with any monitor that meets the specifications provided in the Instructions for Use. (Resolution of 1920x1080 pixels, DVI signal)	32" flat screen, 16:9 aspect ratio, Resolution of 1920x1080 pixels, DVI signal	**Equivalent:** Although the subject device does not provide a monitor, the labeling states that it is compatible with any monitor that meets the same specifications stated in the instructions for use. These are the same specifications as that of the monitor provided with the predicate device.

	Proposed Device	Predicate Device	Equivalence Assessment
Navigation Camera	Navigation System Camera (FP6000) LiveCAM Not provided.	Navigation System Camera (FP6000) With LiveCAM feature.	**Equivalent:** The subject device and the predicate device use the same navigation camera (FP6000). The LiveCAM was an optional component of the NAV3i used to assist the user in orienting the Navigation Camera to the surgical field. The LiveCAM is not required for optimal performance of the system. The color of the enclosure is white compared to the dark grey enclosure of the NAV3i. This is a cosmetic change only and has no effect on device performance and is not a patient contacting component. The cabling for the Navigation camera has been changed from copper based cables to optical fibers. The fiber optic cable provides better signal integrity over the extended distance.
Camera Arm	Camera joint, swing range of 330° when connected to fixed camera arm in the OR	Weight balanced articulated arm, swing range of 330°	**Equivalent:** The purpose of the articulated arm and camera joint are the same; to allow adjustment of the camera position. When fixed to a ceiling mounted arm in the OR, the camera joint provided with the NavSuite®3 Kit provides the same degrees of freedom as the articulated camera arm of the NAV3i predicate device.
Cart with Castors	Not provided	Stainless steel, plastic and fiberglass cart with castors for mobility	**Equivalent:** A cart is not provided with the NavSuite®3 Kit because the components are in a fixed configuration in the OR and are not intended to be mobile.

Substantial Equivalence Conclusion:

Based on the identical indications for use and the technological comparison between the subject device and the predicate device, the minor modifications made to the NavSuite®3 Kit since its previous clearance in K130784 do not alter the intended use or the fundamental scientific technology, and do not raise new questions of safety or effectiveness. Therefore the subject device can be found substantially equivalent to the predicate device.