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

Stryker Corporate
Ms. Becky Ditty
Principal Regulatory Affairs Specialist
4100 East Milham Avenue
Kalamazoo, Michigan 49001

July 7, 2016

Re: K153240
Trade/Device Name: Stryker OrthoMap Express Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 6, 2016
Received: June 7, 2016

Dear Ms. Ditty:

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 Parts 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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)*
K153240

Device Name
Stryker OrthoMap Express Knee system

Indications for Use *(Describe)*
The Stryker OrthoMap Express Knee system, which is comprised of the OrthoMap Express Knee 2.0 Software and a platform of the NAV3i platform family, is intended as a planning and intra-operative guidance system to enable open or percutaneous image-guided surgery.

The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified.

The system is indicated for conditions of the knee joint in which the use of computer assisted surgery may be appropriate.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Section 5. 510(k) Summary

Section 5.1 Submitter

Submitter: Stryker Leibinger GmbH & Co. KG
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Date Prepared: June 23, 2016

Section 5.2 Device

Name of Device: Stryker OrthoMap Express Knee system
Common or Usual Name: Orthopedic Stereotaxic Instrument
Classification Name: §882.4560 – Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO - Orthopedic Stereotaxic Instrument

Section 5.3 Predicate Devices

Primary Predicate	
Name	Stryker Navigation System – Knee Module
510(k) Number	K022579
Description	The Knee Module is a part of the product series of the Stryker Navigation System. The system comprises a knee joint kinematics analysis module based on a wireless optical tracking localization device for use in primary total knee arthroplasty.

Additional Predicates	
Name	PROFESS System (Stryker Nav3/Adapt Platform)
510(k) Number	K141551
Description	The PROFESS™ System, consisting of a computer platform, software and sterile single-use accessories, is designed to enable image guided surgery in intranasal and sinus surgery. Specifically, the system tracks and displays to the surgeon the intraoperative location of Navigated Surgical Instruments, such as suction tools, relative to a CT image. This submission included the NAV3 Platform.
Name	Stryker NAV3i Platform
510(k) Number	K130874
Description	The Stryker Nav3i Platform is a modular component of the Stryker Navigation System and is intended to run Stryker Navigation surgical software for surgical procedures using stereotactic techniques. The surgical navigation software used on this device is cleared as a separate 510(k).
Name	NavSuite3 Kit
510(k) Number	K150301
Description	The NavSuite®3 Kit is a minor modification of the previously cleared Stryker NAV3i Platform. The NavSuite3 Kit consists of the same components that were cleared in K130874 without the mobile cart so that they can be configured and affixed in the operation room suite based on user preferences. The NavSuite3 Kit platform is compatible with the following Stryker Software Application Modules: K131214 CranialMap Neuro Navigation (Including CranialMap Express) and K141941 SpineMap Navigation.

Section 5.4 Device Description

The Stryker OrthoMap Express Knee system is intended to be used as a planning and intraoperative guidance system to enable open or percutaneous image guided knee surgery. The system uses wireless optical tracking technology to display to the surgeon the intraoperative location of navigated surgical instruments relative to a

computed anatomical model of the patient's leg (femur and tibia). The computed model is based on an intra-operative anatomy survey of the leg. The system consists of a Stryker surgical software application (software), which runs on a platform, consisting of a Stryker computer, a navigation camera, an IO-Tablet and a monitor. The Stryker surgical software application interfaces with smart instruments (e.g. patient trackers, instrument trackers or pointers) and several accessories enabling the tracking of surgical instruments.

The Stryker OrthoMap Express Knee 2.0 software is compatible with the NAV3i Platform Family. The NAV3i platform family is a family of platforms that, when used with a surgical software application, 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 NAV3i platform family consists of the following three platforms that have been previously cleared independently or with other Stryker surgical software applications:

- Stryker NAV3 Platform (K141551)
- Stryker NAV3i Platform (K130874)
- Stryker NAVSuite3 Kit (K150301)

The platforms consist of the following components:

- Stryker computer
- Navigation camera
- IO-Tablet
- Monitor
- Mobile cart (if applicable)

Section 5.5 Indications for Use

The Stryker OrthoMap Express Knee system, which is comprised of the OrthoMap Express Knee 2.0 software and a platform of the NAV3i Computer Platform Family, is intended as a planning and intra-operative guidance system to enable open or percutaneous image-guided surgery.

The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified.

The system is indicated for conditions of the knee joint in which the use of computer assisted surgery may be appropriate.

Contraindications:

The surgeon has to determine whether the patient's conditions are appropriate for this kind of procedure or not. A pathological condition against the use of this system could be in some cases advanced osteoporosis or a dysplastic hip.

Section 5.6 Substantial Equivalence Rationale

The intended uses of the subject and predicate devices are similar. The systems are intended as planning and intraoperative guidance systems to enable open or percutaneous computer assisted surgery. Minor modifications were made to the indication for use statement to provide clarification, but do not change the meaning of the indication for use statement.

Both the subject device and the primary predicate device use the same main system components, use similar modes of operation, and use the same localization and tracking technology. Also, both systems use similar accessories (Smart Instruments, Patient Tracker Fixation, Navigated Manual Instruments and other accessories).

The technological characteristics of the subject and predicate device are equivalent. None of the changes alter the operating principle, the control mechanism, the localization and tracking technology, the main system components or the system accuracy performance. The workflow, user interaction, the software architecture and the software features are similar. As demonstrated by the performance testing described in Section 18, the subject device continues to meet the same accuracy specifications as the predicate device. Therefore the differences in technological characteristics to do not raise new questions of safety and effectiveness.

In conclusion, the OrthoMap Express Knee system can be found substantially equivalent to the Stryker Navigation System – Knee Module.

The device comparison table below provides a comparison of the technological characteristics of the subject device to the primary predicate device.

Device Comparison Table

	Subject Device **Stryker OrthoMap Express Knee system**	**Predicate Device - K022579** **Stryker Navigation System – Knee Module**	**Equivalence Assessment**
510(k) Number	Under review	K022579	N/A
Clearance Date	Under review	06/01/2003	N/A
Device Name	Stryker OrthoMap Express Knee system	Stryker Navigation System – Knee System	N/A
Regulation Number	§882.4560 – Stereotaxic Instrument	§882.4560 – Stereotaxic Instrument	**Identical**
Product Code	OLO - Orthopedic Stereotaxic Instrument	HAW – Neurological Stereotaxic Instrument Subsequent Product Code: OLO – Orthopedic Stereotaxic Instrument	**Identical** Both devices fall within the Class II Stereotaxic Instrument regulation. OLO is the Product Code specific to Orthopedic Stereotaxic Instruments and is the most appropriate product code for the subject device.
Product Class	II	II	**Identical**
Localization and Tracking technology	Infrared optical active sensing technology: Infrared light emitted by diodes placed in a known fashion on navigated surgical instruments is sensed by a camera array (navigation camera) on the computer platform, thus allowing for computation of the spatial information.	Infrared optical active sensing technology: Infrared light emitted by diodes placed in a known fashion on navigated surgical instruments is sensed by a camera array (navigation camera) on the computer platform, thus allowing for computation of the spatial information.	**Identical**

	Subject Device **Stryker OrthoMap Express Knee system**	**Predicate Device - K022579** **Stryker Navigation System – Knee Module**	**Equivalence Assessment**
Main System Components	1. Platform 2. OrthoMap Express Knee 2.0 Software 3. Smart Instruments 4. Patient Tracker Fixation 5. Navigated Manual Instruments 6. Instrument Battery, Trays	1. Platform 2. Knee Software 3. Smart Instruments 4. Patient Tracker Fixation 5. Navigated Manual Instruments 6. Instrument Battery, Trays	**Similar**
Compatible Platforms	NAV3i Computer Platform Family: • Stryker NAV3 Platform (SPC-3.1) • Stryker NAV3i Platform (SPC-3.1) • Stryker NAVSuite3 Kit (SPC-3.1)	• Cart I	**Similar**
Registration and Navigation Work Flow	• Patient Preparation • System Setup • Patient Registration (femur) • Navigation (femur) • Patient Registration (tibia) • Navigation (tibia)	• Patient Preparation • System Setup • Patient Registration (femur and tibia) • Navigation (femur and tibia)	**Similar**
System Accuracy	• The system enables the determination of the mechanical axes of the leg as well as cut and component alignment with a mean translational error of < 2 mm and a mean rotational error of < 1°.	The Knee Navigation Module provides a mean system accuracy of • ± 2 mm (translational component) and • ± 1° (rotational component).	**Identical**

	Subject Device **Stryker OrthoMap Express Knee system**	**Predicate Device - K022579** **Stryker Navigation System – Knee Module**	**Equivalence Assessment**
Accessories: Smart Instruments	• Femur Trackers • Tibia Trackers • Instrument Trackers • Pointers	• Femur Tracker • Tibia Tracker • Instrument Tracker • Pointers	**Similar**
Accessories: Patient Tracker Fixation	• ASM Fixation Plate	• Anchoring Pins	**Similar**
Accessories: Navigated Manual Instruments	• Dedicated Mini Jig used for: o Navigation bone resection • ASM Resection Plane Probe used for: o Verification of bone	• Resection Plane Probes, used for: o Navigation bone resection o Verification of bone resection.	**Similar**
Accessories – Other	• Instrument Battery • Sterilization Containers	• Instrument Battery • Sterilization Containers	**Similar**
Additional Software Modifications	• Black-style graphical user interface (GUI) • 16:9 screen ratio • Workflow-oriented application • Recognition of Ortho Grip Knee Pointer and Pointer, Straight • Recognition of nGenius Femur Trackers, nGenius Tibia Tracker, nGenius Universal Tracker	• Grey-style graphical user interface (GUI) • 4:3 screen ratio Workflow-oriented application	**Similar**

Section 5.7 Performance Data

The following performance data were provided in support of the substantial equivalence decision:

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing were conducted on the subject device in accordance with the following standards:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) (FDA Rec# 19-4)

- AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012 (consolidated text) medical electrical equipment -- part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod). (General II (ES/EMC)) (FDA Rec# 19-5)

- IEC 60601-1-2:2007: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (FDA Rec#19-1)

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "MAJOR" level of concern.

Performance Testing – Bench

The following design verification activities have been performed to ensure the correct functionality of the system as it has been specified:

- ASTM accuracy testing verifying the accuracy performance of the localization and tracking technology using the standardized test procedure according to ASTM Standard F2554-10.

- System accuracy testing verifying the specified accuracy of ± 2 mm and ± 1° using a mechanical leg mimicking the patient's anatomy.

- Clinical workflow testing verifying that all system components (application, computer platform and accessories) are compatible. Complete total knee arthroplasty procedures are simulated using Sawbones mimicking the patient's anatomy.

- Functional testing to ensure that all functional requirements are fulfilled.

- Safety testing verifying the effectiveness of all risk controls determined in the device risk analysis and in the risk analyses of the platforms.

This strategy ensures the verification of the accuracy, system integration, software algorithms, system functionality, and correct implementation of the risk control measures. All tests have been successfully completed.

Animal Study

No animal studies were performed to support substantial equivalence.

Clinical Studies

No clinical studies were performed to support substantial equivalence.

Section 5.8 Conclusions

Based on the comparison of intended use and technological characteristics the device is similar to the predicate device. The hardware and software verification and validation testing demonstrate that the subject device meets its performance specifications and will perform as intended in the specified use conditions and that any differences between the subject device and predicate device do not raise new questions of safety and effectiveness. Therefore the subject device can be found substantially equivalent to the predicate device.