



Food and Drug Administration
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Stryker Leibinger Gmbh & Co. Kg
% Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 North Washington Street, Suite 100
Alexandria, Virginia 22314

October 12, 2016

Re: K162341

Trade/Device Name: Stryker OrthoMap Precision Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 18, 2016
Received: August 22, 2016

Dear Ms. Herzog:

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,


Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K162341

Device Name
Stryker OrthoMap Precision Knee system

Indications for Use (Describe)

The Stryker OrthoMap Precision Knee system, which is comprised of the OrthoMap Precision Knee 5.0 Software and a platform of the NAV3i platform family, is intended as a planning and intraoperative 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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 Stryker OrthoMap Precision Knee system is provided below.

Device Common Name: Orthopedic Stereotaxic Instrument

Device Trade Name: Stryker OrthoMap Precision Knee system

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Date Prepared: August 18, 2016

Classification Regulation: §882.4560 – Stereotaxic Instrument

Panel: Orthopedic

Product Code: OLO - Orthopedic Stereotaxic Instrument

Predicate Device: K153240 – Stryker OrthoMap Express Knee system

Indication for Use:

The Stryker OrthoMap Precision Knee system, which is comprised of the OrthoMap Precision Knee 5.0 Software and a platform of the NAV3i platform family, is intended as a planning and intraoperative 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.

Device Description:

The Stryker OrthoMap Precision 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 Precision Knee 5.0 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
- Stryker NAV3i Platform
- Stryker NAVSuite3 Kit

The platforms consist of the following components:

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

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)
- 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 $\pm 1^\circ$ 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.

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 above, the subject device continues to meet the same accuracy specifications as the predicate device. Therefore, the differences in technological characteristics do not raise new questions of safety and effectiveness.

In conclusion, the Stryker OrthoMap Precision Knee system can be found substantially equivalent to the OrthoMap Express Knee system (K153240).

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 Precision Knee System	Predicate Device – K153240 Stryker OrthoMap Express Knee system
510(k) Number	Under review	K153240
Clearance Date	Under review	July 7, 2016
Device Name	Stryker Navigation OrthoMap Precision Knee 5.0 Navigation System	Stryker Navigation OrthoMap Express Knee 2.0 Navigation System
Regulation Number	§882.4560 – Stereotaxic Instrument	§882.4560 – Stereotaxic Instrument
Product Code	OLO - Orthopedic Stereotaxic Instrument	OLO – Orthopedic Stereotaxic Instrument
Product Class	II	II
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.

	Subject Device Stryker OrthoMap Precision Knee System	Predicate Device – K153240 Stryker OrthoMap Express Knee system
Main System Components	Computer Platform OrthoMap Precision Knee 5.0 Software Smart Instruments Patient Tracker Fixation Navigated Manual Instruments Instrument Battery, Trays	Computer Platform OrthoMap Express Knee 2.0 Software Smart Instruments Patient Tracker Fixation Navigated Manual Instruments Instrument Battery, Trays
Compatible Platforms	NAV3i Computer Platform Family: Stryker NAV3 Platform Stryker NAV3i Platform Stryker NAVSuite3 Kit	NAV3i Computer Platform Family: Stryker NAV3 Platform Stryker NAV3i Platform Stryker NAVSuite3 Kit
Registration and Navigation Work Flow	Patient Preparation System Setup Patient Registration (femur and tibia) Analyze Initial Alignment Size and Position Implant Resect Bones Analyze Trial Implant Analyze Final Implant	Patient Preparation System Setup Patient Registration (femur) Navigation (femur) Patient Registration (tibia) Navigation (tibia)
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 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°.
Accessories: Patient / Instrument Trackers	Patient/Instrument Trackers <ul style="list-style-type: none"> • Universal Tracker • Tibia/Pelvic Tracker • Femoral Tracker • nGenius Universal Tracker • nGenius Tibial Tracker • nGenius Femur Tracker • Hip Femur Tracker • Hip Tibia/Pelvis Tracker Pointers <ul style="list-style-type: none"> • Pointer, Knee Navigation • Ortho Grip Knee Pointer • Pointer, Straight 	Femur Trackers / Tibia Trackers <ul style="list-style-type: none"> • Universal Tracker • Tibia/Pelvic Tracker • Femoral Tracker • nGenius Tibial Tracker • nGenius Femur Tracker • nGenius Femur Tracker • Hip Femur Tracker • Hip Tibia/Pelvis Tracker Pointers <ul style="list-style-type: none"> • Pointer, Knee Navigation • Ortho Grip Knee Pointer • Pointer, Straight
Accessories: Patient Tracker Fixation	OrthoLock with OrthoLock Navigation Pin or OrthoLock EX-Pins Anchoring Pins and Insertion Tool	ASM Fixation Plate

	Subject Device Stryker OrthoMap Precision Knee System	Predicate Device – K153240 Stryker OrthoMap Express Knee system
Accessories: Navigated Manual Instruments	Dedicated Mini Jig (which consists of): <ul style="list-style-type: none"> • Adjustment Component • Tracker Adapter • Mini Cutting Guide • Mini Fixation Plate MIS Jig (which consists of): <ul style="list-style-type: none"> • Navigated MIS Jig-A • Navigated MIS Jig-B • Tracker Adapter Plane Probes (Resection Plan Probes and a Posterior Plane Probe)	Dedicated Mini Jig (which consists of): <ul style="list-style-type: none"> • Adjustment Component • Tracker Adapter • Mini Cutting Guide ASM Resection Plane Probe
Screwdrivers	Screwdriver Universal Joint Screwdriver	Screwdriver Universal Joint Screwdriver

Substantial Equivalence Conclusion:

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.