K093206

510(k) Summary

510(k) Owner:	Stryker Leibinger GmbH & Co. KG - Navigation Bötzinger Straße 41 D-79111 Freiburg Germany (p) (+49) 761 45 12 117 (f) (+49) 761 45 12 49 117
Registration No.:	3007582679
Contact Person:	Lilian Eckert email: lilian.eckert@stryker.com Senior Regulatory Affairs Specialist
Date Summary Prepared:	July 29, 2010
Device Trade Name:	Stryker Navigation System – OrthoMap® 3D 1.1 Module
Common Name:	Navigation System
Product Code:	OLO
Classification Name:	Orthopedic Stereotaxic Instrument
Title 21 CFR:	§882.4560
Device Description:	The Stryker Navigation System – OrthoMap® 3D 1.1 Module is part of the product series of the Stryker Navigation System. It is based on a wireless optical tracking localization device. The system comprises of hardware and software for surgical planning and computer assisted surgery. It supports orthopedic oncology procedures, cam type FAI (femoroacetabular impingement) surgery procedures and ACL (anterior cruciate ligament) reconstruction procedures.
Indications for Use:	**Intended Use:** The Stryker Navigation System – OrthoMap® 3D 1.1 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 system offers the following features and functions: • Import of multi-modality image data • Surgical planning, such as image manipulation and visualization and procedural planning • Surgical navigation, such as manual and automatic registration and precise positioning of instruments and implants **Indications:** The system should be operated only by trained personnel such as surgeons and clinic staff. The system can assist surgeons in the following, but not limited to, orthopedic surgical procedures: • Orthopedic oncology procedures • Cam type FAI (femoroacetabular impingement) surgery • ACL (anterior cruciate ligament) reconstruction

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Substantial Equivalence:

The Stryker Navigation System – OrthoMap® 3D 1.1 Module is substantially equivalent in design, intended use and performance to the following predicate devices:

- Stryker Navigation System – OrthoMap® 3D Module (K083009)
- Stryker Navigation System – Cranial Module (K062640)
- BrainLAB VectorVision® ACL (K042512)
- Medtronic Orthopaedic Trauma Application (K050651)

The following verification and validation activities were performed:

Performance Testing (Bench):

- Bench testing according to Stryker Navigation's procedures for product design and development: It includes software code reviews, component, functional, integration, safety and accuracy testing. It shows that the product meets the requirements. Also, it shows that no software anomalies impacting safety and effectiveness are known.
- Cadaveric verification studies evaluating the overall system and clinical accuracy when used for FAI or ACL treatment. The analysis of the data revealed that the specified acceptance criteria for system and clinical accuracy can be reached for cam type FAI and ACL treatments.

Performance Testing (Clinical):

- Clinical confirmative trials: The system has been used clinically for cam type FAI treatments. The trials confirm the results of bench testing and the cadaveric verification study. They also show that the system can be used safely and effectively in the clinical environment.
- Comprehensive literature review discussing the safety and effectiveness during usage of other navigation devices for FAI and ACL procedures. The review shows that other devices using equivalent characteristics and functionality can be used safely and effectively for cam type FAI and ACL procedures.

Conclusion:

The combination of the results of the bench testing, the cadaveric verification study, and the clinical confirmative trials demonstrate the safety and effectiveness of the system when used for the cam type FAI and ACL procedures. No new types of issues of safety and effectiveness are introduced by using this device.

The literature review and the comparison to the predicate devices show that the device makes use of equivalent technological characteristics and functionality and is intended for equivalent surgical procedures as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Stryker Leibinger GmbH & Co. KG
% Ms. Lilian Eckert
Senior Regulatory Affairs Specialist
Bötzinger Straße 41
D-79111 Freiburg, Germany

Re: K093206
Trade/Device Name: Stryker Navigation System - OrthoMap® 3D 1.1 Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 29, 2010
Received: August 02, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

Indications for Use Statement

510(K) Number (if known): K093206

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Device Name: Stryker Navigation System – OrthoMap® 3D 1.1 Module

Intended Use:

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Indications:

The system should be operated only by trained personnel such as surgeons and clinic staff.
The system can assist surgeons in the following, but not limited to, orthopedic surgical procedures:

- Orthopedic oncology procedures
- Cam type FAI (femoroacetabular impingement) surgery
- ACL (anterior cruciate ligament) reconstruction

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093206