K072271

4100 E. Milham Avenue
Kalamazoo, MI 49001
t: 269 323 7700 f: 800 965 6505
www.stryker.com

stryker®

Instruments

510(k) Summary

Device Sponsor:

Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-323-7700
(f) 269-324-5412

DEC 1 8 2007

Registration No.: 1811755

Trade Name: Stryker® Navigation System – iNfinitus Hip Resurfacing Module

Common Name: Navigation System

Classification Name: Stereotaxic Instruments

Equivalent to: K022365 Stryker Navigation – Hip Module
K063028 VectorVision Hip SR

Device Description:

Stryker® Navigation System – iNfinitus Hip Resurfacing Module is part of the product series of the Stryker® Navigation System. The system comprises software for intraoperative surgical planning and supports computer assisted surgery based on a wireless optical tracking localization device for the use in navigated hip resurfacing surgery.

The Stryker® Navigation System – iNfinitus Hip Resurfacing Module is based on the previously cleared Stryker® Navigation System – Hip Module. The Hip Resurfacing module is tailored to the workflow of hip resurfacing procedures and consists of planning and preparing the acetabular side with depth to seat measurement for the cup and planning and preparation tasks for the femoral component.

Intended Use:

Stryker® Navigation System – iNfinitus Hip Resurfacing Module
The **Stryker® Navigation System – iNfinitus Hip Resurfacing 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 surgery may be appropriate, and where a reference to a rigid anatomical structure such as but not limited to the pelvis, or femur, can be identified.

Indications for Use:

The system is indicated for partial hip resurfacing, to assist in precise positioning of hip femoral resurfacing component.

The system must be used within the operating room and should be operated only by trained personnel such as orthopedic surgeons and clinic staff.

Contraindications

• An immobile hip due to an existing condition, such as rheumatoid arthritis, previous fracture, or fusion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2007

Stryker Corporation
% Ms. Becky Ditty
Regulatory Affairs
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K072271
Trade/Device Name: Stryker Navigation System – iNfinitus Hip Resurfacing Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: December 12, 2007
Received: December 13, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K072271

Device Name: Stryker Navigation System – iNfinitus Hip Resurfacing Module

Intended Use

The Stryker Navigation System –iNfinitus Hip Resurfacing 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 surgery may be appropriate, and where a reference to a rigid anatomical structure such as but not limited to the pelvis, or femur, can be identified.

Indications for Use

The system is indicated for partial hip resurfacing, to assist in precise positioning of the femoral resurfacing component.

The system should be operated only by trained personnel such as orthopedic surgeons and clinic staff.

Contraindication

- An immobile hip due to an existing condition, such as rheumatoid arthritis, previous fracture, or fusion.
- Surgical situation where increasing surgical time may be detrimental to the patient.

Prescription Use X and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072271