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

APR 2 1 2005

stryker®

Instruments

K050615

510(k) Summary

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

Registration No.: 1811755

Trade Name: Stryker Navigation System – CT Based Hip Module

Common Name: Navigation System

Classification Name: Stereotactic Instruments

Equivalent to: K022365 Stryker Navigation – Hip Module
K993239 Stryker Navigation – Neuro Module
K010602 VectorVision Hip System

Device Description:

Stryker Navigation System – CT Based Hip Module
The CT Based Hip Module is part of the product series of the Stryker Navigation System. The system comprises a computer assisted hip implantation control and monitoring module based on a wireless video-optical tracking localization device for the use in total hip arthroplasty. The CT-Based Hip module will allow the importation of CT scans into the system. Unique to other hip navigators the Stryker system provides Surgeons with pre-operative, intraoperative and postimplantation assessments of the patient's joint kinematics. The system supports different surgical protocols. The order of femoral and acetabular preparation is configurable as well as other user specific settings. The user settings adjust the workflow and the graphical interface sequence in order to match the user habits.

Intended Use:

Stryker Navigation System – CT Based Hip Module
The Stryker Navigation System – CT Based Hip 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 should be operated only by trained personnel such as orthopedic surgeons and clinic staff.

The Stryker Navigation System – CT Based Hip Module supports, but is not limited to the following surgical procedures

- Any form of Total Hip Athroplasty (THA), e.g. open or minimal-invasive
- Precisely position instruments, implants and bony tissue during orthopedic surgery, such as operations performed with Hip and bones in the upper extremities
- Revisions

Substantial Equivalence (SE) Rational:

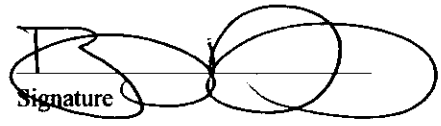
The Stryker Navigation System – CT Based Hip Module are equivalent in intended use, safety, and effectiveness to existing devices being marketed by Stryker and BrainLab.

Safety and Effectiveness:

The Stryker Navigation System – CT Based Hip Module do not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Navigation System – CT Based Hip Module are substantially equivalent to these existing devices. They will be designed and manufactured in accordance with Stryker Leibinger's and Stryker Instrument's Quality Management System covered by QSR 21CFR 820.

Submitted by:

Becky Ditty
Regulatory Affairs Representative



Signature

Date submitted:

8-Mar-05

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2005

Ms. Becky Ditty
Regulatory Affairs Representative
Stryker Instruments, Inc.
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K050615
Trade/Device Name: Stryker Navigation System-CT Based Hip Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: March 8, 2005
Received: March 10, 2005

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.

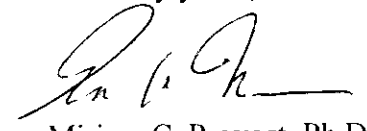
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K050615

Device Name: Stryker Navigation System – CT Based Hip Module

Intended Use:

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- Revisions

Prescription Use ___X___ (per 21 CFR 801 Subpart D) or Over-The-Counter Use _____ (per 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)

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K050615