K022365

# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS: STRYKER NAVIGATION – HIP MODULE

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## General Information

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|---|---|
| Proprietary Name: | Stryker Navigation System – Hip Module<br><br>HipTrac |
| Common Name: | Image Guided Surgery System |
| Classification Name(s): | Instrument, Stereotaxic |
| Classification Code(s): | 84HAW |
| Submitter: | Stryker Corporation<br>Stryker Leibinger<br>4100 East Milham Avenue<br>Kalamazoo, MI 49001<br>800-253-7370 |
| Submitter's Registration #: | 1811755 |
| Manufacturer's Registration #: | 8010177 |
| Contact Person: | Kelli J. Bitterburg<br>Regulatory Affairs Associate<br>Phone: 616-324-5346 x4026<br>Fax: 616-324-5454 |
| Summary Preparation Date: | July 19, 2002 |

## Summary of Safety and Effectiveness:

The Stryker Navigation System – 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.

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

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

- Any form of Total Hip Athroplasty (THA), e.g. open of 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

The Stryker Navigation System is equivalent in intended use, safety, and effectiveness to existing image guided surgery systems being marketed by companies such as Stryker, Sofamor Danek, and BrainLab.

They Stryker Navigation System does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Navigation System is substantially equivalent to these existing devices.

Kelli J. Bitterburg
Regulatory Affairs Associate

Dated: 7/19/02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2003

Ms. Kelli Bitterburg
Regulatory Affairs Associate
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K022365
Trade Name: Stryker Navigation System - Hip Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: October 25, 2002
Received: October 28, 2002

Dear Ms. Bitterburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K022365

Device Name: Stryker Navigation System – Hip Module

**Intended Use:**

The Stryker Navigation System – 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 must be used within the operating theatre and should be operated only by trained personnel such as orthopedic surgeons and clinic staff.

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

- Any form of Total Hip Athroplasty (THA), e.g. open of minimal-invasive
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- Revisions

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use _____
(per 21 CFR 801.109)

Miriam C. Provost (Optional Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number K022365