K022579 1/2

JUN - 2 2003

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS: STRYKER NAVIGATION SYSTEM – KNEE MODULE TRADITIONAL 510(K)

General Information

Proprietary Name:	Stryker Navigation System – Knee Module
Common Name:	Image Guided Surgery System
Classification Name(s):	Stereotaxic Instrument
Classification Code(s):	84 HAW
Submitter:	Stryker Corporation Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Kelli J. Bitterburg Regulatory Affairs Associate Phone: 616-324-5346 x4026 Fax: 616-323-4215
Summary Preparation Date:	August 2, 2002

Device Description

The Knee Module is a part of the product series of the Stryker Navigation System. The system comprises a knee joint kinematics analysis module based on a wireless video-optical tracking localization device for the use in primary total knee arthroplasty.

Intended Use

The Stryker Navigation System – Knee Module is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery. The system is indicated for conditions of the knee joint in which the use of computer assisted surgery may be appropriate.

The surgeon has to determine whether the patient's conditions are appropriate for this kind of procedure or not. A pathological condition against the use of this system could be in some cases advanced osteoporosis or a displastic hip.

The Stryker Navigation System provides precise stereotactic determination of surgical targets using a stereotactic methodology. The three principle features include computer calculation of stereotactic coordinates from the diagnostic images, measurement of stereotactic coordinates within the surgical field, high-resolution computer display of diagnostic images with stereotactic coordinates indicated. The system is comprised of hardware and software components.

Substantial Equivalence

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, Medtronic, Brainlab and Aesculap.

The 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: 6/2/03

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2003

Kelli Bitterburg
Regulatory Agent
Stryker Leibinger
4100 E. Milham Ave.
Kalamazoo, MI 49001

Re: K022579
Trade/Device Name: Stryker Navigation System-Knee Module
Regulation Number: 21 CFR 882.4650
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: March 3, 2003
Received: March 4, 2003

Dear Ms. Bitterburg:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Miriam C. Provost

for 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): _____

Device Name: Stryker Navigation System – Knee Module

Intended Use:

The Stryker Navigation System – Knee Module is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery. The system is indicated for conditions of the knee joint in which the use of computer assisted surgery may be appropriate.

Contraindications:

The surgeon has to determine whether the patient's conditions are appropriate for this kind of procedure or not. A pathological condition against the use of this system could be in some cases advanced osteoporosis or a displastic hip.

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

_____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K022579

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

(Optional Format 1-2-96)