

AUG 19 2002

510(k) Summary

***Smith & Nephew Image Guided Surgical System
for Knee Applications***

Submitter's name: Smith & Nephew, Inc., Orthopaedic Division
Submitter's address: 1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number: 901-399-6707
Contact person: Gino J. Rouss
Date summary prepared: July 25, 2002
Trade or proprietary device name: Smith & Nephew Image Guided Surgical System for Knee Applications
Common or usual name: Stereotaxic Instrument
Classification name: Stereotaxic Instrument
Device Class: Class II
Device Product Code: HAW
Panel Code: Neurology / 84

Subject device description:

The Smith & Nephew Image Guided Surgical System for Knee Applications is intended to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. The Smith & Nephew Image Guided Surgical System for Knee Applications uses image-guided arrays to transmit or reflect infrared LEDs (light emitting diodes) that are emitted by an IGS Platform System. This allows the instruments to be recognized and tracked in real time in the surgical field.

Subject device intended use:

The Smith & Nephew Image Guided Surgical System for Knee Applications is indicated for use in total knee procedures, including but not limited to, primary and revision total knee arthroplasty and unicompartmental knee arthroplasty, in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure, such as a long bone can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.

Technological Characteristics:

The devices included in this 510(k) are substantially equivalent to the following devices:

Smith & Nephew Image Guided Surgical Instruments for Knee Applications

510(k) K012938

Medtronic Surgical Navigation Technologies

510(k) K012937

Performance data was provided to support the claim of substantial equivalence.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2002

Smith & Nephew, Inc.
Gino Rouss
Clinical/Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K022460

Trade/Device Name: Smith & Nephew Image Guided Surgical System for Knee
Applications

Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: July 25, 2002
Received: July 26, 2002

Dear Mr. Rouss:

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.

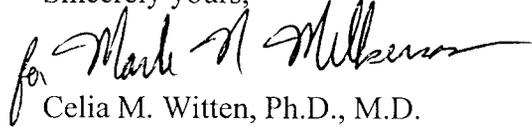
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Gino Rouss

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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" (21 CFR Part 807.97). 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,

for *Celia M. Witten*

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): K022460

Device Name: Smith & Nephew Image Guided Surgical System for Knee Applications

Indications For Use:

The Smith & Nephew Image Guided Surgical System for Knee Applications is indicated for use in total knee procedures, including but not limited to, primary and revision total knee arthroplasty and unicompartmental knee arthroplasty, in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure, such as a long bone can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use *[Signature]*
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

for *Mark A. Miller*
(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K022460