K021815

510(k) Summary
Image Guided Surgical Instruments For Trauma Applications and Universal Accessories

OCT 17 2002

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:	May 30, 2002
Trade or proprietary device name:	Smith & Nephew Image Guided Surgical Instruments for Trauma Applications and Universal Accessories
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 Instruments for Trauma Applications are instruments that have been modified to allow image-guided arrays (Fighters) to be fixed onto the instruments. The image-guided arrays can use either infrared LEDs (light emitting diodes) or universal accessories (passive spheres) to transmit or reflect the infrared LEDs (light emitting diodes) that are emitted by an IGS Platform System. Along with commercially available software, this will allow the instruments to be recognized and tracked in real time in the surgical field. The universal accessories (passive spheres) will be available as either sterile or non-sterile and are for single use only. Each package will contain a multiple number of spheres. The infrared LEDs (light emitting diodes) or universal accessories (passive spheres) do not come in contact with the open wound during surgical procedures. The image-guided arrays that are affixed to the instruments work in conjunction with reference frames that are rigidly attached to the anatomy. Each reference frame is also fitted with either infrared LEDs (light emitting diodes) or universal accessories (passive spheres) to transmit or reflect the infrared LEDs (light emitting diodes) that are emitted by the IGS Platform System. The reference frames will allow the IGS Platform System to continuously track the position of the anatomy during navigation. If any movement of the IGS Platform System or anatomy is detected, the system can compensate for it, thereby maintaining accurate navigation.

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A. *Applicable 510(k)'s*

Image Guided Instruments for Trauma Applications			
Manufacturer	***Submission Name***	***Exhibit No.***	***FDA Clearance Date***
Surgical Navigation Technologies	StealthStation	10	1-24-96
Surgical Navigation Technologies	StealthStation™ System – ENT Application Addendum	11	1-21-98
Surgical Navigation Technologies	StealthStation® FluoroNav™ Module	12	4-22-99
Surgical Navigation Technologies	Indications Modifications for the StealthStation System	13	2-22-00
Surgical Navigation Technologies	StealthStation Generation 3	14	5-3-00
BrainLAB AG	VectorVision® Trauma	15	3-14-02
BrainLAB AG	VectorVision2	16	5-19-99
Smith & Nephew, Inc.	Image Guided Surgical Instruments for Knees	17	2-8-02
Surgical Navigation Technologies	Knee Module For The StealthStation™ System	18	1-25-02
Surgical Navigation Technologies	StealthStation™ System Passive Instrument Option	19	9-16-97

Subject device intended use:

Image Guided Surgical Instruments for Trauma Applications are intended to be used with the ***Universal Accessories*** to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. ***Image Guided Surgical Instruments for Trauma Applications*** are indicated for use in surgical trauma procedures, in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure such as a long bone (femur, tibia, humerus, radius, ulna, fibula), pelvic bone (including acetabular), calcaneus, and talus bone can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.

Example procedures include but are not limited to:

Spinal procedures and spinal implant procedures such as pedicle screw placement
Pelvis and acetabular fracture treatment such as screw placement or ilio-sacral screw fixation
Fracture treatment procedures, such as intramedullary nailing or plating or screwing or external fixation procedures in the tubular bones
Fracture reduction procedures
High Tibia Osteotomy

Technological Characteristics:

Image Guided Surgical Instruments for Trauma Applications are similar to currently legally marketed Class II stereotactic instruments in that they incorporate infrared LED (light emitting diodes) or ***Universal Accessories (passive spheres)*** onto the instruments that allow the instruments to be recognized and tracked in real time in the surgical field.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

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

Re: K021815
Trade/Device Name: Smith & Nephew Image Surgical Instruments for Trauma Applications
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 18, 2002
Received: July 22, 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.

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" (21CFR 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,

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): K021815

Device Name: **Image Guided Surgical Instruments for Trauma Applications and Universal Accessories**

Indications For Use:

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Example procedures include, but are not limited to:

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Pelvis and acetabular fracture treatment such as screw placement or ilio-sacral screw fixation
Fracture treatment procedures, such as intramedullary nailing or plating or screwing or external fixation procedures in the tubular bones

Additional procedures include:

Fracture reduction procedures

High Tibia Osteotomy

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021815