K033341

SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 1 0 2004

SMITH & NEPHEW IMAGE-GUIDED SURGICAL INSTRUMENTS FOR HIP APPLICATIONS

CONTACT PERSON
Janet Johnson Akil
Director, Regulatory Affairs
(901) 399-5153

ADDRESS
Smith & Nephew, Inc., Orthopaedic Division
1450 East Brooks Road
Memphis, TN 38116

DEVICE DESCRIPTION

Subject of this Premarket Notification are the Smith & Nephew Image Guided Surgical Instruments for Hip Applications for use on the BrainLAB VectorVision^2 Hip Navigation System. Along with the associated hip software, the image guided surgical instruments for hip applications can be recognized and tracked in real time in the surgical field. Smith & Nephew has previously received clearance for Image-Guided Instruments and Software for Hip Applications under K021798 for use on the Medtronic Surgical Navigation Technologies StealthStation® Platform Systems. The Smith & Nephew Image Guided Surgical Instruments for Hip Applications have been developed in order to utilize the intra-operative image-guided technology to track the immediate location and position of the surgical instruments during surgical hip procedures using the BrainLAB VectorVision^2 Hip Navigation System.

INDICATIONS FOR USE

The Indication / Intended Use of the Smith & Nephew Image-guided Hip Instrumentation and the BrainLAB VectorVision System, as described in its labeling, has not changed as a result of the modifications. The indications for use for the BrainLAB VectorVision^2 Hip Navigation System are the same as the indications cleared for market by FDA through 510(k) K040368. The system is intended to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. Smith & Nephew Image Guided Surgical Instruments for Hip Applications are indicated for use in surgical hip 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 can be identified relative to a CT based model or fluoroscopic image of the anatomy or by an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. These procedures include but are not limited to, acetabular cup placement as part of a partial or total hip arthroplasty (primary or revision).

TECHNOLOGICAL CHARACTERISTICS

The Smith & Nephew Image Guided Surgical System for Hip Applications uses the same Fundamental Scientific Technology found in the following Premarket Notifications:

DESCRIPTION	510(K)	CLEARANCE
STRYKER NAVIGATION – HIP MODULE	K022365	1/22/03
VECTORVISION HIP	K010602	9/12/01
STEALTHSTATION SYSTEM HIP MODULE	K021980	11/19/02
NAVITRACK SYSTEM – TOTAL HIP REPLACEMENT	K022364	2/04/03
SMITH & NEPHEW IMAGE-GUIDED SURGICAL INSTRUMENTS FOR HIP APPLICATIONS	K021798	12/09/02
VECTORVISION HIP	K040368	8/23/04

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2004

Ms. Janet Johnson Akil
Director, Regulatory Affairs
Smith and Nephew, Inc.
Orthopedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K033341
Trade/Device Name: Smith & Nephew Image-Guided Surgical Instruments for Hip Applications
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: August 31, 2004
Received: September 1, 2004

Dear Ms. Akil:

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. 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,

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

Indications for Use

510(k) Number (if known): K033341

Device Name: Smith & Nephew Image-Guided Surgical instruments for Hip Applications

Indications For Use:

Image Guided Surgical Instruments for Hip Applications are intended to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. Image Guided Surgical Instruments for Hip Applications are indicated for use in surgical hip 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 can be identified relative to a CT based model or fluoroscopic image of the anatomy or by an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. These procedures include but are not limited to, acetabular cup placement as part of a partial or total hip arthroplasty (primary or revision).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K033341