K021980

Summary of Safety and Effectiveness
Hip Module Software for the StealthStation® System

I. Manufacture:

Medtronic Surgical Navigation Technologies
826 Coal Creek Circle
Louisville, CO 80027 USA
Telephone Number: (720) 890-3200
Fax Number: (720) 890-3500

NOV 1 9 2002

II. Contact:

Victoria G. Rendon
Clinical and Regulatory Affairs Associate
Medtronic Surgical Navigation Technologies

III. Product Name/ Classification Name:

Product Name: **Hip Module for the StealthStation® System**
Classification Name: **Stereotaxic Instrument** (21 CFR 882.4560)
Classification Panel: **84 HAW**

IV. Date Summary Submitted

June 13, 2002

V. Description of Device Modification:

This submission allows a surgeon to utilize a modified version of the FluoroNav™ Software to place hip implants and repair and/or stabilize trauma sustained to the pelvic area. The Hip Module for the StealthStation® System is technically equivalent to the StealthStation® System, and the FluoroNav™ Module for the StealthStation®. All systems use either active or passive infrared markers to track a reference frame attached to the anatomy and to track surgical instruments. This information is correlated to the patient's CT, MR or fluoroscopic images of the anatomy.

This submission provides new orthopedic indications that are substantially equivalent to the named predicate devices' indications statement.

VI. Substantial Equivalence:

The Hip Module for the StealthStation® System was substantially equivalent to the StealthStation System cleared in previous 510(k)'s. Additionally, the Hip Module was determined to be substantially equivalent to the BrainLAB VectorVision Hip, and the Stryker Navigation System – Spine & Fluoroscopy Module. As required by risk analysis, all verification and validation activities were performed by designated individual(s) and the results demonstrated substantial equivalence.

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VII. Indications For Use:

The indications for use for the Hip Module for the StealthStation® Software are identical to the indications for use for the named predicate devices. The indications for use are as follows:

The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.

The Hip Module for the StealthStation is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedures:

Minimally Invasive Orthopedic Procedures

Total Hip Replacement (Primary and Revision)

Tumor Resection and Bone/Joint Reconstruction

Placement of Iliosacral Screws

Femoral Revision

Stabilization and Repair of Pelvic Fractures (Including But Not Limited To Acetabular Fractures)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

Medtronic Surgical Navigation Technologies
Victoria G. Rendon
Clinical and Regulatory Affairs Associate
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K021980
Trade/Device Name: Hip Module for the Stealthstation System
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: October 25, 2002
Received: October 28, 2002

Dear Ms. Rendon:

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" (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,

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): K021980

Device Name: **Hip Module for the StealthStation® System**

Indications For Use:

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Femoral Revision

Stabilization and Repair of Pelvic Fractures (Including But Not Limited To Acetabular Fractures)

(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)

(Optional Format 1-2-96)

Miriam C Provost

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

Number K021980