JUN 2 - 2005

K050438

Summary of Safety and Effectiveness
StealthStation® System Update

I. **Manufacturer**

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: (720) 890-3217
Fax Number: (720) 890-3517

II. **Contact**

Tina Dreiling
Associate Regulatory Affairs Specialist
Medtronic Navigation, Inc.

III. **Product Name / Classification**

Common Name:	Stereotaxic instrument
Classification Name:	Instrument, Stereotaxic
Trade Name:	StealthStation® System Update

Stereotaxic instrument - Class II as described in 21 CFR § 882.4560
Product Code: HAW

IV. **Date Summary Submitted**

February 18, 2005

V. **Description of Device Modification**

This submission provides an update to the StealthStation® System, including a new computer hardware and operating system options, a passive-only optical digitizer option, new cranial reference frame and EM reference frame.

VI. **Substantial Equivalence**

The StealthStation® System Updates were shown to be substantially equivalent to the StealthStation® System cleared in previous 510(k) submissions. As required by risk analysis, all verification and validation activities were performed by designated individuals and the results demonstrated the substantial equivalence.

K050938

VII. **Indications for Use**

This submission does not change the indications for use for the StealthStation System.

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, fluoroscopy images, or digitized landmarks of the anatomy.

For the optical-based and EM-based system, example procedures include, but are not limited to:

Cranial Procedures:
Cranial Biopsies
Tumor Resections
Craniotomies/ Craniectomies
Skull Base procedures
Thalamotomies/Pallidotomies
Pituitary Tumor Removal
CSF Leak Repair
Pediatric Catheter Shunt Placement
General Catheter Shunt Placement

Orthopaedic Procedures:
Total Knee Arthroplasty (Primary and Revision)
Unicompartmental Knee Arthroplasty

Spinal Procedures:
Spinal Implant Procedures, such as Pedicle Screw Placement

ENT Procedures:
Transphenoidal Procedures
Intranasal Procedures
Orbital Nerve Decompression Procedures
Optic Nerve Decompression Procedures
Polyposis Procedures
Endoscopic Dacryocystorhinostomy
Encephalocele Procedures
Sinus procedures, such as Maxillary Antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid Explorations, Turbinate Resections, and Frontal Sinusotomies

Additional example procedures for the optical-based system include, but are not limited to:

Total Knee Arthroplasty (Primary and Revision)
Unicompartmental Knee Arthroplasty
Minimally Invasive Orthopaedic Procedures
Pediatric Orthopaedics
Total Hip Replacement (Primary and Revision)
Periacetabular Osteotomies
Tumor Resection and Bone/Joint Reconstruction
Femoral Revision
Placement of Iliosacral Screws
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

JUN 2 - 2005

Ms. Tina Dreiling
Associate Regulatory Affairs Specialist
Medtronic Navigation Incorporated
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K050438
Trade/Device Name: StealthStation® System Update
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: May 16, 2005
Received: May 17, 2005

Dear Ms. Dreiling:

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.

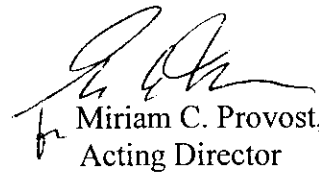
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115 . 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/industry/support/index.html.

Sincerely yours,



for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050438

Device Name: StealthStation® System Update

Indications for Use

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Femoral Revision
Placement of Iliosacral Screws
Stabilization and Repair of Pelvic Fractures (Including but not limited to Acetabular Fractures)

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Restorative
Devices

K050438