

K043088 1/2

JAN - 5 2005 Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module

Summary of Safety and Effectiveness
Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module

777 701 1115 1111
777 701 15 11 23

- I. **Manufacturer**
Medtronic Surgical Navigation Technologies
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 Surgical Navigation Technologies

- III. **Product Name / Classification**
Product Name: Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module
Classification Name: Stereotaxic Instrument (21 CFR 882.4560)
Classification Panel: 84 HAW

- IV. **Date Summary Submitted**
December 13, 2004

- V. **Description of Device Modification**
This submission describes updates made to the Imageless Knee Module for the StealthStation to enable this application to be used in conjunction with the AxiEM™ electromagnetic navigation technology.

- VI. **Substantial Equivalence**
The Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module is shown to be substantially equivalent to the Imageless Hip Module and the GoldenEye Micro-Magnetic Tracking System Option cleared in previous 510(k)s. As required by risk analysis, all verification and validation activities performed by designated individuals and the results demonstrated substantial equivalence.

K043088 2/2

Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module

VII. Indications for Use

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, fluoroscopy images, or digitized landmarks of the anatomy.

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

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

Orthopaedic Procedures:

- Total Knee Arthroplasty (Primary and Revision)
- Unicompartmental Knee Arthroplasty
- Minimally Invasive Orthopaedic Knee Procedures



JAN - 5 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K043088

Trade/Device Name: Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: November 4, 2004
Received: November 8, 2004

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.

Page 2 - Ms. Tina Dreiling

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/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

Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module

510(k) Number (if known): K043088

Device Name: Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module

Indications for Use:

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, fluoroscopy images, or digitized landmarks of the anatomy.

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

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

Orthopaedic Procedures:

Total Knee Arthroplasty (Primary and Revision)
Unicompartmental Knee Arthroplasty
Minimally Invasive Orthopaedic Knee Procedures

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

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

Page 1 of 1

510(k) Number K043088