K061248

AUG 31 2006

Summary of Safety and Effectiveness
AxiEM™ Imageless Hip Module for the StealthStation® System

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: Imageless Hip Module for the StealthStation® System
Stereotaxic instrument - Class II as described in 21 CFR § 882.4560
Product Code: HAW

IV. **Date Summary Submitted**

April 28, 2006

V. **Description of Device Modification**

The AxiEM™ Imageless Hip Module for the StealthStation® System provides a mechanism for the establishment of stereotactic coordinates without the use of a pre-operative or intra-operative image using electromagnetic navigation

VI. **Substantial Equivalence**

The primary difference between the Imageless Hip Module for the StealthStation® System and the AxiEM™ Imageless Hip Module for the StealthStation® System is that the AxiEM™ Imageless Hip Module utilizes electromagnetic navigation technology rather than optical tracking.

The primary difference between the AxiEM™ Imageless Knee Module for the StealthStation® System and the AxiEM™ Imageless Hip Module for the StealthStation® System is that the subject device navigates instruments for use in hip procedures and the AxiEM™ Imageless Knee application navigates instruments for use in knee procedures.

As required by risk analysis, all verification and validation activities will be performed by designated individuals and will demonstrate the safety and effectiveness of the device.

The information provided in this 510(k) application supports that the AxiEM™ Imageless Hip Module for the StealthStation® System is substantially equivalent to the Imageless Hip Module for the StealthStation® System (K052623).

VII. **Indications for Use**

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.

The AxiEM™ Imageless 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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2006

Medtronic Navigation, Inc.
% Ms. Tina Dreiling
Associate RA Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K061248
Trade/Device Name: AxiEM™ Imageless Hip Module for the StealthStation® System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: August 9, 2006
Received: August 10, 2006

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.

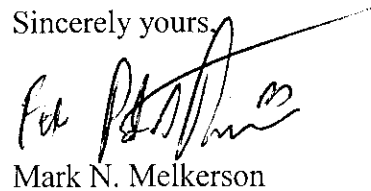
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
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): K061248

Device Name: AxiEM™ Imageless Hip Module for the StealthStation® System

Indications for Use:

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Total Hip Replacement (Primary and Revision)

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 OF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K061248