K020338

FEB 2 7 2002

Summary of Safety and Effectiveness
StealthStation® with FluoroMerge™ Software

I. Manufacture:

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

II. Contact:

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

III. Product Name/ Classification Name:

Product Name: **StealthStation® with FluoroMerge™ Software**
Classification Name: **Stereotaxic Instrument** (21 CFR 882.4560)
Classification Panel: **84 HAW**

IV. Date Summary Submitted

January 30, 2002

V. Description of Device Modification:

This submission describes updates made to the StealthStation® System to include an optional software package that enables a user to merge a patient's pre-operative dataset with a patient's intra-operative dataset.

VI. Substantial Equivalence:

The StealthStation® with the FluoroMerge™ was shown to be substantially equivalent to the StealthStation System cleared in previous 510(k)'s. As required by risk analysis, all verification and validation activities were performed by designated individual(s) and the results demonstrated substantial equivalence.

VII. Indications For Use:

The indications for use for the FluoroMerge™ Software are identical to the StealthStation® System 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 or fluoroscopy images of the anatomy.

Example procedures include, but are not limited to:

Cranial Procedures:
Cranial biopsies
Craniotomies/Craniectomies
Skull base procedures
Thalamotomies/Pallidotomies
Pituitary tumor removal
CSF Leak Repair

Spinal Procedures:
Spinal implant procedures, such as pedicle screw procedures

ENT Procedures:
Transphenoidal procedures
Intranasal procedures
Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies /Sphenoid explorations, Turbinate resections, and Frontal sinusotomies
Orbital Decompression Procedures
Optic Nerve Decompression Procedures
Polyposis Procedures
Endoscopic Dacryocystorhinostomy
Encephalocele Procedures

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2002

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

Re: K020338
Trade/Device Name: StealthStation® with FluoroMerge™ Software
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 30, 2002
Received: February 1, 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" (21CFR 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,

for Mark N Melkerson

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): K020338

Device Name: StealthStation® with FluoroMerge™ Software

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

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

510(k) Number K020338