510(k) Premarket Notification for Medtronic Navigation, Inc.'s
StealthViz Advanced Planning Application with StealthDTI Package

510k Summary   **JUL 1 8 2008**

May 16, 2008

Subject:	510(k) Summary of Safety and Effectiveness Information for the StealthViz Advanced Planning Application with StealthDTI Package
Submitter:	John Adams Regulatory Affairs Manager Medtronic Navigation, Inc. 826 Coal Creek Circle Louisville, CO 80027
Proprietary Name:	StealthViz Advanced Planning Application with StealthDTI Package
Common Name and Classification:	Picture Archival and Communications System
Device Description:	StealthViz is a general purpose 2D/3D surgical planning and image review and analysis software application running on a standard computer. It enables:

- importing digital diagnostic and functional imaging datasets (e.g. MR, MRA, CT, CTA, fMRI, X-ray, DSA, PET, SPECT, MEG, MSI, US) across a LAN, the internet or a modem, or via local transfer from physical media (e.g. CD, DVD, USB drive),

- reviewing and analyzing the data (e.g. making measurements) in various 2D and 3D presentation formats,

- performing image fusion (co-registration) of datasets using automated or a manual image-matching technique,

- segmenting structures in the images with manual and automatic tools and converting them into 3D objects for display,

- creating hybrid datasets by filling in segmented regions slice-by-slice on anatomical datasets, and

- exporting results to other Medtronic Navigation planning applications, to a PACS or to other Medtronic Navigation surgical navigation systems such as the StealthStation System.

The StealthDTI Package provides the following additional capabilities:

- import diffusion-weighted sequence datasets (gradients),

- co-register the gradients with anatomical studies using an automatic

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algorithm or a manual technique,

- perform diffusion tensor calculations to create intermediate datasets such as Fractional Anisotropy and Apparent Diffusion Coefficient and the ability to display these results with, for example, Directionally Encoded Color or grayscale mapping,

- enable the user to define regions-of-interest (ROI) from which to perform white matter tractography (WMT, also known as fiber tracking). The user can define multiple ROIs or use previously segmented objects as ROIs (e.g. an fMRI activation area that has been segmented into a 3D object).

- calculated fiber tracts can be displayed and converted into 3D objects,

- all results can be exported as noted for the base StealthViz application description.

Intended Use: StealthViz is a software application indicated for use in 2D/3D surgical planning and image review and analysis. It enables:
- importing digital diagnostic and functional imaging datasets (e.g. MR, MRA, CT, CTA, fMRI, X-ray, DSA, PET, SPECT, MEG, MSI, US)
- reviewing and analyzing the data in various 2D and 3D presentation formats,
- performing image fusion (co-registration) of datasets,
- segmenting structures in the images with manual and automatic tools and converting them into 3D objects for display,
- exporting results to other Medtronic Navigation planning applications, to a PACS or to Medtronic Navigation surgical navigation systems such as the StealthStation System.

The StealthDTI Package is a subset of StealthViz that implements a special case of segmenting 3D structures from the datasets. It is indicated for use in the processing of diffusion-weighted MRI sequences into 3D objects that represent white-matter tracts.

Only DICOM for presentation images can be used on an FDA approved monitor for mammography for primary image diagnosis. Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.

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Test
Discussion:
Testing was performed in two phases. Testing was performed by Visage Imaging, the third party developer, to ensure that all Requirements were met by the product. This testing is referenced in the Trace Matrix which ensures that all requirements were successfully verified.

A subset of testing was also performed in-house to verify compatibility with the Stealth application. This is represented in Product Design Verification and Validation Testing protocols/reports.

Test
Conclusion:
Results of the testing performed by Visage Imaging, as well as in-house testing, demonstrate that the StealthDTI package is as safe, as effective, and performs as well as or better than the legally marketed device.

Medtronic Navigation, Inc.
% Mr. Kevin Morningstar
Senior Consultant
Morningstar Consulting Group LLC
3025 Perry Street
DENVER CO 80212

JUL 1 8 2008

Re: K081512
    Trade/Device Name: Stealth Viz Advanced Planning Application with StealthDTI Package
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Picture archiving and communications system
    Regulatory Class: II
    Product Code: LLZ
    Dated: May 16, 2008
    Received: May 30, 2008

Dear Mr. Morningstar:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,
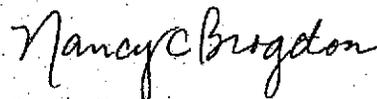
Nancy C. Brogdon
Director, Division of Reproductive,
    Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: StealthViz Advanced Planning Application with StealthDTI Package

Indications for Use: **Intended Use:**

StealthViz is a software application indicated for use in 2D/3D surgical planning and image review and analysis. It enables:

- importing digital diagnostic and functional imaging datasets (e.g. MR, MRA, CT, CTA, fMRI, X-ray, DSA, PET, SPECT, MEG, MSI, US)
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Prescription Use ___X___   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE).

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number _____*K081512.*_____