

K130608

## 510(k) Summary

February 27, 2012

- I. Company:** Medtronic Navigation, Inc.  
826 Coal Creek Circle  
Louisville, Colorado 80027 USA  
Telephone Number: 720-890-3200  
Fax Number: 720-890-3500
- Contact:** Sharon McDermott  
Senior Regulatory Affairs Specialist

AUG 07 2013

**Proprietary Trade Name:**

Quadcut®, 3.0 mm x 13 cm  
Quadcut®, 3.4 mm x 13 cm  
Quadcut®, 4.3 mm x 13 cm

- II. Common Name:** Stereotaxic Instrument
- III. Classification Name:** Stereotaxic Instrument (21 CFR 882.4560)
- IV. Classification:** Class II (21 CFR 882.4560)
- V. Product Code:** HAW
- VI. Product Description:**

The navigated Quadcut® is a sterile, single use surgical instrument intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck and otoneurological surgery. Quadcut® is an accessory component of the StraightShot M4 handpiece, which is an integral part of the XPS and IPC Systems. The XPS and IPC systems provide power to drive the blades during ENT procedures.

Quadcut® is intended for attachment to the M4 hand piece for use in conjunction with Fusion ENT software on a Medtronic computer-assisted surgery system. Each blade has a tracker mounted on it to allow for navigation during the ENT surgical procedure. The system's mobile emitter generates a low-energy magnetic field to locate the tracker mounted on the blade. Then, the software displays the location of the blade's tip within multiple patient image planes and other anatomical renderings.

**VII. Indications for Use:**

The XPS/IPC System is intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery.

The Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use 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, can be identified relative to a CT- or MR-based model, or digitized landmarks of the anatomy.

The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgment.

**VIII. Identification of Legally Marketing Devices (Predicate Devices)**

Description	510(k) Number	Clearance Date
StealthStation Golden Eye Micro-Magnetic Tracking System Option	K001284	06/12/2000
Quadcut® (non-navigated), Class I (Product code: EQJ)	Exempt	NA

**IX. Comparison of the Technological Characteristics:**

Item	Subject Devices	Predicate Devices
Quadcut Blades Indications for Use	<p>The XPS/IPC System is intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery.</p> <p>The Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use 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, can be identified relative to a CT- or MR-based model, or digitized landmarks of the anatomy.</p> <p>The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgment.</p>	<p><i>Medtronic Xomed Quadcut Blades (non-navigated) Class I, 510(k) Exempt Same intended use</i></p> <p><i>StealthStation Golden Eye Micro-magnetic System. K001284 Same intended use</i></p>
Establishment of Stereotactic Coordinates (Tracking Method)	Electromagnetic	<p><i>StealthStation Golden Eye Micro-magnetic System. K001284</i></p> <p><i>Same</i></p>
System Accuracy Requirement	<p>Benchtop and simulated environment:</p> <p>95% confidence / 99.5% reliability, as dictated by risk analysis, of <math>\leq 3.00</math> mm.</p>	<p><i>StealthStation Golden Eye Micro-magnetic System. K001284</i></p> <p><i>Equivalent</i></p>
Materials -- blade	304L stainless steel	<p><i>Medtronic Xomed Quadcut Blades (non-navigated) Class I, 510(k) Exempt</i></p> <p><i>Same material</i></p>
M4 Hub	ABS hub	<p><i>Medtronic Xomed Quadcut Blades (non-navigated)</i></p> <p><i>Class I, 510(k) Exempt</i></p> <p><i>Same materials</i></p>
Sterilization Method	Ethylene Oxide sterilization	<p><i>Medtronic Xomed Quadcut Blades (non-navigated)</i></p> <p><i>Class I, 510(k) Exempt</i></p> <p><i>Same sterilization method</i></p>

The subject devices have the same intended use and technological characteristics as the predicate devices.

**X. Discussion of the Performance Testing**

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. Specifically, testing with Medtronic Navigation systems and Fusion software was conducted to ensure acceptable navigational accuracy. Test samples were subjected to simulated real-life use conditions during functional testing.

**XI. Conclusions**

The navigated Quadcut® has been shown through comparison and testing to be substantially equivalent to the identified predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

August 7, 2013

Medtronic Navigation  
% Ms. Sharon McDermott  
Senior Regulatory Affairs Specialist  
826 Coal Creek Circle  
Louisville, CO 80027

Re: K130608

Trade/Device Name: Quadcut  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic Instrument  
Regulatory Class: Class II  
Product Code: HAW  
Dated: June 25, 2013  
Received: June 25, 2013

Dear Ms. McDermott:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Eric A. Mann -S**

for Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic and Ear, Nose  
and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number: K130608

### Device Name:

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The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgment.

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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## Eric A. Mann -S

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(Division Sign-Off)  
Division of Ophthalmic and Ear, Nose  
and Throat Devices  
510(k) Number \_\_\_\_\_