



Food and Drug Administration
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April 7, 2016

Medtronic Navigation, Inc.
Carey Brenner
Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, CO 80027

Re: K153555
Trade/Device Name: EM ENT Navigated Suctions
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: March 7, 2016
Received: March 8, 2016

Dear Carey Brenner:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,


Denise L. Hampton -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 (if known)
K153555

Device Name
ENT EM Fusion and Supplemental Navigated Instruments

Indications for Use (Describe)

EM ENT Instruments are indicated for use in navigated ENT procedures to locate points on patient anatomy relative to a CT-based or MR-based digital model and to remove fluids, semi-fluid substances, tissue, and bone dust. EM ENT Instruments are indicated for use with Medtronic computer-assisted surgery systems. The EM ENT instruments are indicated for use in ENT procedures such as:

- CSF leak repairs related to ENT procedure
- Intranasal procedures
- Orbital decompression procedures
- Polyposis procedures
- Endoscopic dacryocystorhinostomy
- Sinus procedures, such as maxillary antrostomies
- Ethmoidectomies
- Sphenoidotomies/sphenoid explorations
- Turbinate resections and frontal sinusotomies

The EM ENT instruments can also be used in the ENT surgical approach for the following procedures:

- Pituitary tumor removal
- Skull base procedures
- Transsphenoidal procedures
- Optic nerve decompression procedures
- Encephalocele procedures

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Electromagnetic (EM) ENT Navigated Suctions

510(k) Summary

December 11, 2015

- I. Company: Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: 720-890-3200

Contact: Carey Brenner
Regulatory Affairs Specialist
- II. Proprietary Trade Name:

EM ENT Navigated Suctions
- III. Classification Name:

Stereotaxic Instrument
- IV. Classification:

21 CFR 882.4560 Stereotaxic Instrument
- V. Product Codes:

PGW
- VI. Product Description

The Electromagnetic Ear Nose & Throat (EM ENT) Navigated Suctions are electromagnetically tracked, handheld, re-usable instruments intended to be used with EM ENT Instrument Trackers and ENT software on a Medtronic computer-assisted surgery system. The EM ENT Instrument Tracker is attached to the EM ENT Navigated Suction to track its position. The navigation system's mobile emitter generates a low-energy magnetic field to locate the tracker mounted on the instrument. Then, the software displays the location of the instrument's tip within multiple patient image planes and other anatomical renderings.

VII. Indications for Use

EM ENT Instruments are indicated for use in navigated ENT procedures to locate points on patient anatomy relative to a CT-based or MR-based digital model and to remove fluids, semi-fluid substances, tissue, and bone dust. EM ENT Instruments are indicated for use with Medtronic computer-assisted surgery systems. The EM ENT instruments are indicated for use in ENT procedures such as:

- CSF leak repairs related to ENT procedure
- Intranasal procedures
- Orbital decompression procedures
- Polyposis procedures
- Endoscopic dacryocystorhinostomy
- Sinus procedures, such as maxillary antrostomies
- Ethmoidectomies
- Sphenoidotomies/sphenoid explorations
- Turbinate resections and frontal sinusotomies

The EM ENT instruments can also be used in the ENT surgical approach for the following procedures:

- Pituitary tumor removal
- Skull base procedures
- Transsphenoidal procedures
- Optic nerve decompression procedures
- Encephalocele procedures

VIII. Summary of the Technological Characteristics

	<i>Subject Device:</i> EM ENT Navigated Suction Devices	<i>Predicate Devices:</i>
Indications for Use	<p><u>EM ENT Navigated Suctions and Trackers</u></p> <p>EM ENT Instruments are indicated for use in navigated ENT procedures to locate points on patient anatomy relative to a CT-based or MR-based digital model and to remove fluids, semi-fluid substances, tissue, and bone dust. EM ENT Instruments are indicated for use with Medtronic computer-assisted surgery systems. The EM ENT instruments are indicated for use in ENT procedures such as:</p> <ul style="list-style-type: none"> •CSF leak repairs related to ENT <p>The EM ENT instruments can also be used in the ENT surgical approach for the following procedures:</p> <ul style="list-style-type: none"> • Pituitary tumor removal • Skull base procedures • Transsphenoidal procedures • Optic nerve decompression procedures • Encephalocele procedures 	<p><i>Medtronic Manual Suctions (non-navigated) Class I, 510k Exempt</i> <i>Same intended use</i></p> <p><i>StealthStation® System GoldenEye™ Micro-Magnetic Tracking System Option</i> <i>Same Indications for use</i></p> <p><i>StealthStation® System Update</i> <i>Same Indications for use</i></p>

	<p>procedure</p> <ul style="list-style-type: none"> •Intranasal procedures •Orbital decompression procedures •Polyposis procedures •Endoscopic dacryocystorhinostomy •Sinus procedures, such as maxillary antrostomies •Ethmoidectomies •Sphenoidotomies/sphenoid explorations •Turbinate resections and frontal sinusotomies 	
Localization Technology	Electromagnetic (proximal tracker attached)	<p><i>StealthStation® System GoldenEye™ Micro-Magnetic Tracking System Option Same</i></p> <p><i>StealthStation® System Update Same</i></p>
System or Instrument Accuracy Requirements	<p><u>EM ENT Navigated Suctions</u></p> <p>Within a standard controlled environment: navigated peg errors of 1.54 mm at 95% confidence and 99% reliability</p> <p>Within a simulated surgical environment: navigated peg errors of 1.73 mm at 5% confidence and 99% reliability</p>	<p><i>StealthStation® System GoldenEye™ Micro-Magnetic Tracking System Option Equivalent</i></p> <p><i>StealthStation® System Update Equivalent</i></p>
Suction Functionality	Yes	<i>Medtronic Manual Suctions (non-navigated) Class I, 510k Exempt Substantially Equivalent</i>
Instrument Tip Configurations	Standard (straight) Angle Olive Ball/Angle	<i>Medtronic Manual Suctions (non-navigated) Class I, 510k Exempt Substantially Equivalent</i>
Materials	<p><u>EM ENT Navigated Suctions</u></p> <p>Stainless Steel, titanium</p> <p><u>Patient and Instrument Trackers</u></p> <p>Patient contacting cable: AES Santoprene® 8281-90 material with Colorant Pantone 301C</p>	<p><i>Medtronic Manual Suctions (non-navigated) Class I, 510k Exempt Same Material as Suction</i></p> <p><i>StealthStation® System Update Same Material as Tracker Cable</i></p>
Instrument Shaft Configurations	Fixed- Straight, Small Straight, 45° frontal, 70° curve, 90° curve, 90° frontal	<i>Medtronic Manual Suctions (non-navigated) Class I, 510k Exempt Substantially equivalent</i>
Supplied as “Reusable Use”	<p><u>EM ENT Navigated Suctions</u></p> <p>Yes</p> <p><u>Patient and Instrument Trackers</u></p> <p>Supplied Sterile Single Use</p>	<i>Medtronic Manual Suctions (non-navigated) Class I, 510k Exempt reusable</i>

IX. Identification of Legally Marketing Devices (Predicate Devices)

Description (Substantial Equivalence Characteristic)	510(k) Number	Clearance Date
Manual Surgical Instruments (non-navigated), Class I (product code: LRC Regulation: 21CFR 874.4420)	Exempt	Not Applicable ^a
StealthStation [®] GoldenEye [™] Micro-Magnetic Tracking System Option	K001284	06/12/2000
StealthStation [®] System Update	K050438	06/02/2005

^a The Class I Medtronic ENT suction devices were released to market on June 6, 1997. They were recently sold to another company in 2014.

X. Discussion of the Performance Testing

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. Specifically, testing with the StealthStation[®] System and EM ENT Suction instruments was conducted to ensure acceptable navigational accuracy, suction capability, conformance to design specifications and electrical safety testing. Test samples were subjected to simulated real-life use conditions including repeated functional testing.

XI. Conclusions

The EM ENT Navigated Suction Instruments have been shown through comparative and bench testing to be substantially equivalent to the identified predicate devices.