MAR 1 3 2014

K133665

510(k) Summary

November 27, 2013

I. **Company**: Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: 720-890-3200
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Contact: Charles Copperberg
Principal Regulatory Affairs Specialist
Telephone number: 720-890-2291
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Proprietary Trade Name: Malleable Suction™ Instruments

Description	Part Number
Malleable Suction Small, Standard Tip	9735015
Malleable Suction Medium, Standard Tip	9735016
Malleable Suction Medium, Angle Tip	9735017
Malleable Suction Medium, Ball Tip	9735018
Malleable Suction Large, Standard Tip	9735019

II. **Common Name**: Stereotaxic Instrument

III. **Classification Name**: Stereotaxic Instrument (21 CFR 882.4560)

IV. **Classification**: Class II (21 CFR 882.4560) Ear, Nose and Throat Devices

V. **Product Code**: PGW

VI. **Product Description:**

The Malleable Suction instruments are sterile, single use instruments intended for use with the ENT software applications on a Medtronic computer assisted surgery systems, StealthStation® systems (S7, i7 and Fusion®). The Malleable Suction instruments are electromagnetically navigated devices that are designed to be bendable by hand into a shape by the user in order to customize the instrument to the needs of the surgeon for each individual patient's anatomy and disease.

Each Malleable Suction instrument incorporates a tracking system within the instrument tip. The mobile emitter of the navigation system generates a low-energy magnetic field

to locating the tracker mounted within the tip of the instrument. The navigation system software displays the location of the instrument's tip within multiple patient image planes and other anatomical renderings.

The instrument attaches to, and functions with, standard surgical vacuum suction systems and comes with a cleaning stylet to assist in dislodging blockages.

VII. Indications for Use:

The Malleable Suction™ Instrument is indicated for use in ENT procedures where surgical navigation or image-guided surgery may be necessary to locate and remove fluids, semi-fluid substances, tissue, and bone dust. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and Medtronic ENT software.

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.

The Malleable Suction™ Instrument is indicated for use in the following procedures:

- Pituitary tumor removal only ENT procedures
- CSF leak repair only related or from an ENT procedure
- Skull base procedures for ENT access
- Transsphenoidal procedures
- Intranasal procedures
- Optic nerve decompression procedures
- Orbital decompression procedures
- Polyposis procedures
- Endoscopic dacryocystorhinostomy
- Encephalocele procedures
- Sinus procedures, such as maxillary antrostomies
- Ethmoidectomies
- Sphenoidotomies/sphenoid explorations
- Turbinate resections and frontal sinusotomies

VIII. Identification of Legally Marketed Devices (Predicate Devices)

The Malleable Suction Instruments have the same intended use and technological characteristics as the predicate devices shown in the following tables.

Predicate Devices

Predicate Description	510(k) Number	Clearance Date	Predicate Substantial Equivalence Characteristic
StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option	K001284	06/12/2000	Electromagnetic Navigation technology
Medtronic Quadcut	K130608	08/07/2013	Suction and Navigation
Medtronic ENT Suction Devices	Medtronic Letter to File (MOD-058 which references K001284 K050438)	7/26/2010	PNs 9734307, 9734308 – suction comparison and , 9734309 and 9734310 – navigation accuracy comparison
StealthStation System Update	K050438	06/02/2005	Inclusion of ENT procedures in indications for use

IX. Comparison of the Technological Characteristics:

Item	Subject Devices (Malleable Suction Instruments)	Predicate Devices
Indications for Use	The Malleable Suction™ Instrument is indicated for use in ENT procedures where surgical navigation or image-guided surgery may be necessary to locate and remove fluids, semi-fluid substances, tissue, and bone dust. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and Medtronic ENT software. 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 Malleable Suction™ Instrument is indicated for use in the following procedures: Pituitary tumor removal only ENT procedures, CSF leak repair only related or from an ENT procedure, Skull base procedures for ENT access, Transphenoidal procedures, Intranasal procedures, Optic nerve decompression procedures, Orbital decompression procedures Polyposis procedures, Endoscopic dacryocystorhinostomy, Encephalocele procedures, Sinus procedures, such as maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/sphenoid explorations, Turbinate resections and frontal sinusotomies	***StealthStation Golden Eye Micro-magnetic System. K001284*** 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: ENT Procedures: Transphenoidal procedures, Intranasal procedures, Sinus procedures such as Maxillary antrostromies, Ethmoidectomies, Sphenoidotomies/sphenoid explorations, Turbinate resections, and frontal sinusotomies. ***Medtronic Reusable, Navigated Suction Devices K050438*** 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. For the optical based and EM based system, example procedures include, but are not limited to: ENT Procedures: Transphenoidal procedures, Intranasal procedures, optical nerve decompression procedures, optic nerve decompression procedures, polyposis procedures, endoscopic dacryocystorhinostomy, encephalocele procedures, Sinus procedures such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/sphenoid explorations, Turbinate resections, and frontal sinusotomies. ***Medtronic Quadcut K130608*** 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.

Item	Subject Devices (Malleable Suction Instruments)	Predicate Devices
Establishment of Stereotactic Coordinates (Tracking Method)	Electromagnetic, tip tracking	***StealthStation® GoldenEye™ Micro-Magnetic Tracking System (K001284) - Electromagnetic (Tip Tracked)*** ***Medtronic ENT Suction Devices (MOD-058 (K001284 and K050438))*** Electromagnetic, proximal tracking
System Accuracy Requirement	Bench-top and simulated environment: 95% confidence / 99.5% reliability, as dictated by risk analysis, of $\leq$ 3.00 mm.	***Medtronic ENT Suction Devices (MOD-058 (K001284 and K050438))*** 95% confidence / 99.5% reliability, as dictated by risk analysis, of $\leq$ 3.00 mm. ***Equivalent*** ***StealthStation® GoldenEye™ (K001284)*** 95% confidence / 99.5% reliability, as dictated by risk analysis, of $\leq$ 3.00 mm. ***Equivalent***
Suction Capabilities	Capable of removing fluids, semi-fluid substances, tissue, and bone dust.	***Medtronic ENT Suction Devices (MOD-058 (K001284 and K050438))*** ***Equivalent***
Shaft Flex/Configurations	Bendable, configuration surgeon defined	***Medtronic ENT Suction Devices (MOD-058 (K001284 and K050438))*** Fixed, Straight, 45° curve, 90° curve
Tip Configurations	Standard (straight), Angle, Ball	***Medtronic ENT Suction Devices (MOD-058 (K001284 and K050438))*** Standard (straight), Angle, Ball
Materials	Aluminum shaft Pebax Liner LCP Tip Polyester Shrink tubing	***Medtronic ENT Suction Devices (MOD-058 (K001284 and K050438))*** Stainless Steel, Titanium
Sterile/ Reusable	Sterile, Single Use	***Medtronic ENT Suction Devices (MOD-058 (K001284 and K050438))*** Reusable, clean and sterilize prior to use

X. Discussion of the Performance Testing

Testing was completed to ensure the functionality and compatibility with the identified Medtronic navigation systems. The following table summarizes the performance testing completed:

Test	Description
Accuracy	Tested navigated instrument in 2D and 3D space
Accelerated Life Functionality	Tested navigated instruments functionality after accelerated life exposures and user conditions
Simulated Use	Tested instruments according to user's needs and intended use.
Sterilization	Verified the ability to effectively EO sterilize the instruments (SAL 10^{-6}) and that EO residuals are within the defined limits.
Shipping	Tested instruments and packaging after simulated shipping conditions
General Requirements and Performance	Tested instruments to assure conformance with identified design and performance specifications
Tool Cards	Verified the Malleable Suction Tools package has met the required interface needs of the application software
Electrical Safety	Verified conformance to IEC 60601-1 and IEC 60601-1-2, electrical safety and EMC standards
Chemical Resistance	Tested exposure of Malleable Suction instruments to substances common to ENT procedures

XI. Conclusions

The Malleable Suction Instruments have been shown through comparison and testing to be substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 13, 2014

Medtronic Navigation, Inc.
% Mr. Charles M. Copperberg
Principal Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, CO 80027

Re: K133665
Trade/Device Name: Malleable Suction™ Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Ear, Nose, and Throat Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: February 6, 2014
Received: February 7, 2014

Dear Mr. Copperberg:

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" (21CFR 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,

Deborah L. Falls -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):

Device Name: Malleable Suction Instruments

Indications for Use:

The Malleable Suction™ Instrument is indicated for use in ENT procedures where surgical navigation or image-guided surgery may be necessary to locate and remove fluids, semi-fluid substances, tissue, and bone dust. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and Medtronic ENT software.

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- Turbinate resections and frontal sinusotomies

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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