K132297

510(k) Summary

July 23, 2013

I. **Company:** Medtronic Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, Florida 32216 USA
Telephone Number: 904-332-8233
Fax Number: 904-296-2386

NOV 0 5 2013

Contact: Rozanne Paciej
Regulatory Affairs Manager

Proprietary Trade Name: To Be Determined

II. **Common Name**: EM Sinus Dilation System

III. **Classification Name**: Ear, Nose, and Throat Manual Surgical Instrument (21 CFR 874.4420)

IV. **Classification**: Class I (21 CFR 874.4420)

V. **Product Code**: LRC

VI. **Product Description:**
The EM Sinus Dilation System composes of sterile, single-use instruments that combine electromagnetic (EM) "plug and play" tracking capability with the pathway expansion effects of balloon dilatation technology and an inflator. Each of the three types of sinus seekers (frontal, maxillary and sphenoid) has a unique shape with the appropriate angle that allow for entry into the scarred sinus outflow tract. The inflator consists of a plunger, barrel and extension tube.

Each sinus dilation instrument is intended to be used in conjunction with the Fusion software on a Medtronic computer-assisted surgery system.

Inside of each sinus seeker is an EM tracker. The emitter on the Fusion System generates a low-energy magnetic field to locate the tracker mounted on the sinus seeker. Then, the software displays the location of the sinus dilation instrument's tip within multiple patient image planes and other anatomic renderings. After confirmation of placement, the sinus seeker's balloon can be inflated with saline solution, using the inflator to expand the outflow track of the targeted sinus.

VII. Indications for Use:

The EM Sinus Dilation System is intended for use in sinus procedures when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, sphenoid sinuses.

The EM Sinus Dilation system is used in conjunction with the Medtronic computer-assisted surgery system.

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)

EM Dilation Sinus System is substantially equivalent in intended use and performance characteristics to the follow predicate devices:

Description	510(k) Number	Clearance Date
ENTrigue Sinus Dilation System	K121351	08/29/2013
XprESS Multi-Sinus Dilation Tool	K102003	10/22/2010

The table comparing the proposed and predicate devices is presented on the next page.

IX. Comparison of the Technological Characteristics:

Product/510(k) Number	EM Sinus Dilation System Proposed	ENTrigue Sinus Dilation System K121351 Predicate	XprESS Multi-Sinus Dilation Tool K102003 Predicate
Clearance Date	TBD	08/29/2012	10/22/2010
Product Code and Classification	LRC/Class I	LRC/Class I	LRC/Class I
Device Description	The EM Sinus Dilation System composes of sterile, single-use instruments that combine electromagnetic (EM) "plug and play" tracking capability with the pathway expansion effects of balloon dilatation technology and an inflator. Each of the three types of sinus seekers (frontal, maxillary and sphenoid) has a unique shape with the appropriate angle that allow for entry into the scarred sinus outflow tract. The inflator consists of a plunger, barrel and extension tube. Each sinus dilation instrument is intended to be used in conjunction with the Fusion software on a Medtronic computer-assisted surgery system. Inside of each sinus seeker is an EM tracker. The emitter on the Fusion System generates low-energy magnetic field to locate	The ENTrigue Sinus Dilation System consists of a disposable balloon which is mounted on a reusable delivery instrument to allow for dilation of sinus ostia in the paranasal cavity under endoscopic guidance. The Sinus Balloon components include a balloon sleeve to slide over the tip of the delivery instrument, a connecting collar to latch the balloon sleeve to the delivery instrument, and an inflation line to connect to the balloon inflation device. The features of this device enable a physician to guide the device to the sinus ostium using endoscopic visualization.	The XprESS Multi-Sinus Dilation Tool is intended to remodel or recreate the sinus outflow tract via trans-nasal balloon dilation. The XprESS device combines features of a curved suction tip and a frontal ostium seeker with the tissue expansion effect of a balloon dilation. The familiar features of this device enable a physician to track the device to the sinus ostium using endscopic visualization. Since the distal end of the device is re-shapeable, one balloon can be modified to work on multiple sinuses within the same patient. The XprESS Multi-Sinus Dilation Tool has been tested to withstand multiple inflations and

	the tracker mounted on the sinus seeker. Then, the software displays the location of the sinus dilation instrument's tip within multiple patient image planes and other anatomic renderings. After confirmation of placement, the sinus seeker's balloon can be inflated with saline solution by using the inflator to expand the outflow track of the targeted sinus.		device tip manipulations (up to 25) in a surgical case wherein all 6 sinus ostia are being dilated. The XprESS device curved suction tip has a 2mm atraumatic ball tip with a 1 mm inside diameter. A suction tube may be connected to the proximal barbed fitting to provide active suction.
Intended use	The EM Sinus Dilation System is intended for use in sinus procedures when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, and sphenoid sinuses. The EM Sinus Dilation system is used in conjunction with the Medtronic computer-assisted surgery system. 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	The ENTrigue Sinus Dilation System is intended for use in the surgical procedures to access, examine or treat the nasal and paranasal tissues leading to the ostia.	To access and treat the frontal recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remolded by balloon displacement of adjacent bone and paranasal sinus structures.

	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.		
Common Name/Classification Name	Sinus Balloon Dilation System ENT Manual Surgical Instrument	Sinus Dilation System	Sinus Balloon Dilation System ENT Manual Surgical Instrument
Tracking Method	Electromagnetic	Device cannot connect to IGS for tracking.	Device is compatible with IGS.
System Accuracy Method	Benchtop and simulated environment	Not applicable	Not applicable
Predicate	XprESS Multi-Sinus Dilation Tool (K102003) ENTrigue Sinus Dilation System (K121351)	Entellus Medical Inc. XprESS Multi-Sinus Dilation Tool (K102003)	XprESS Multi-Sinus Dilation Tool (K093007) FinESS Sinus Treatment System (K081542)
Method of Action	Reusable instrument for dilation of sinus with balloon attached using navigation	Reusable instrument for dilation of sinus with balloon sleeve.	Reshapeable balloon used in multiple sinuses, suction tip,
Balloon Size	3 balloon sizes (5mm, 6mm, and 7mm)	10mm long, 6mm diameter balloon (only one size	18mm long; 5,6 and 7mm diameters LoProfile

		specified) this balloon is a sleeve	

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

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" a comparison of key characteristics demonstrates that the proposed EM Sinus Dilation System is substantially equivalent to the predicate device in terms of performance characteristics. The EM Sinus Dilation System is as safe, as effective, and performs as well as the 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 20993-002

June 16, 2014

Medtronic Xomed, Inc.
c/o Ms. Rozanne Paciej
Regulatory Affairs Manager
6743 Southpoint Drive North
Jacksonville, FL 32256

Re: K132297
Trade/Device Name: EM Sinus Dilation System
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: October 8, 2013
Received: October 8, 2013

Dear Ms. Paciej:

This letter corrects our substantially equivalent letter of November 5, 2013.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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 (if known): K132297

Device Name:

EM Sinus Dilation System

Indications for Use:

The EM Sinus Dilation System is intended for use in sinus procedures when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, and sphenoid sinuses.

The EM Sinus Dilation system is used in conjunction with the Medtronic computer-assisted surgery system.

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____.
(Part 21 CFR 801 Subpart D) (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)

Vasant G. Malshet