DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 1, 2015

Medtronic Xomed, Inc.
Ms. Gabriela Anchondo
Regulatory Affairs
6743 Southpoint Drive North
Jacksonville, FL 32216

Re: K152121
Trade/Device Name: Nuvent 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 30, 2015
Received: November 2, 2015

Dear Ms. Anchondo:

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,

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): K152121

Device Name:

EM Sinus Dilation System

Indications for Use:

The EM Sinus Dilation System is intended for use in conjunction with the Medtronic Computer-Assisted Surgery System during sinus procedures when surgical navigation or image-guided surgery may be necessary. When used concomitantly, these systems may be used to

- locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia; or
- locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses that is scarred, granulated or previously surgically altered to facilitate dilation of the sinus ostia.

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 _____
(Per 21 CFR 801 Subpart D) (Per 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)

5. 510(k) Summary

[807.92(a)(1)] 510(k) Owner

Name	Medtronic Xomed, Inc.
Address	6743 Southpoint Drive North Jacksonville, FL 32216 USA
Phone and Fax Numbers	Phone: (904) 279-7550 Fax: (904) 296-2386
Name of Contact Person	Gabriela Anchondo Regulatory Affairs Manager
Date Summary Prepared	July 24, 2015

[807.92(a)(2)] Name of Device

Trade or Proprietary Name	NuVent™ EM Sinus Dilation System
Common or Usual Name	EM Sinus Dilation System
Classification Name	Ear, nose and throat manual surgical instrument (21 CFR 874.4420, Product Code LRC)

[807.92(a)(3)] Legally Marketed Device

Predicate Device	K132297 EM Sinus Dilation System

[807.92(a)(4)] Description of Device

Device Description	The NuVent™ EM Sinus Dilation System comprises sterile, single-use instruments that combine electromagnetic (EM) “plug and play” tracking capability with the pathway expansion effects of balloon dilation technology and an inflator. Each of the three types of sinus seekers (frontal, maxillary and sphenoid) has a unique shape and angle that allows for entry into the sinus outflow tract. The inflator consists of a plunger, barrel and extension tube. Each sinus seeker is intended for use in conjunction with the Fusion software on a Medtronic computer-assisted surgery system. Inside each sinus seeker is an EM tracker. The emitter on the EM Computer-Assisted Surgery System generates a low-energy magnetic field to locate the tracker mounted inside of the sinus

	seeker. The software displays the location of the sinus seeker's tip within multiple patient image planes and other anatomic renderings. After confirmation of placement, the sinus seekers balloon can be inflated with saline solution by using the inflator to expand the outflow of the targeted sinus.
[807.92(a)(5)] Intended Use	
Indications for Use Statement	The EM Sinus Dilation System is intended for use in conjunction with the Medtronic Computer-Assisted Surgery System during sinus procedures when surgical navigation or image-guided surgery may be necessary. When used concomitantly, these systems may be used to • locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia; or • locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses that is scarred, granulated or previously surgically altered to facilitate dilation of the sinus ostia. 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.
Difference in Indications from Predicate Device	The difference in indications for use is supported by clinical data and does not affect the safety and effectiveness of the device.

[807.92(a)(6)] Technological Characteristics

Comparison The subject device has the same technological characteristics as the predicate device. The only difference is in the indications for use. Refer to the table that follows for a comparison.

Attributes	EM Sinus Dilation System (Subject Device)	EM Sinus Dilation System (Predicate Device)	Comparison
510(k) No.	K152121	K132297	--
510(k) Submitter	Medtronic Xomed	Medtronic Xomed	SAME
Class & Reg	Class I -21 CFR 874.4420	Class I - 21 CFR 874.4420	SAME
Product Code & Class Name	LRC - ENT Manual Surgical Instrument	LRC - ENT Manual Surgical Instrument	SAME
Intended Use	The EM Sinus Dilation System is intended for use in conjunction with the Medtronic Computer-Assisted Surgery System during sinus procedures when surgical navigation or image-guided surgery may be necessary. When used concomitantly, these systems may be used to • locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to **facilitate dilation of the sinus ostia**; or • locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses that is **scarred, granulated or previously surgically altered** to **facilitate dilation of the sinus ostia**. 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	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.	SAME with exception of: **“scarred, granulated and previously surgically altered”:** This use has been validated in a human clinical study. **“facilitate dilation of the sinus ostia.”** This use was previously cleared via K132297 as supported by cadaver data. The cleared instructions for use included instructions about the dilation of the sinus ostia. However, the indications for use statement did not. The dilation of the sinus ostia is now being added to the indications for use for clarity.

Attributes	EM Sinus Dilation System (Subject Device)	EM Sinus Dilation System (Predicate Device)	Comparison
	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.		
Location Method	Location of tissue accomplished via electromagnetic (EM) “plug and play” tracking capability using image guidance (IG).	Location of tissue accomplished via electromagnetic (EM) “plug and play” tracking capability using image guidance (IG).	SAME
Movement Method	Movement of tissue accomplished using a rigid seeker with unique angles to allow entry of frontal, maxillary or sphenoid sinuses.	Movement of tissue accomplished using a rigid seeker with unique angles to allow entry of frontal, maxillary or sphenoid sinuses.	SAME
Dilation Method	Balloon is inflated with saline solution by using the inflator to expand outflow track of targeted sinus ostia.	Balloon is inflated with saline solution by using the inflator to expand outflow track of targeted sinus ostia.	SAME
Balloon Size	5mm, 6mm and 7mm	5mm, 6mm and 7mm	SAME
Patient Contacting Materials	SAME	SAME	SAME
Tracking Method	Electromagnetic	Electromagnetic	SAME
System Accuracy	Clinical environment	Benchtop and simulated environment	No device changes were implemented as a result of the proposed expanded indications; therefore, no additional benchtop or simulated environment testing was required to demonstrate substantial equivalence. The system accuracy for a patient population with scarred, granulated and previously surgically altered tissue was verified with a clinical study.
Method of Action	Reusable instrument for dilation of sinus ostia with balloon attached using navigation.	Reusable instrument for dilation of sinus ostia with balloon attached using navigation.	SAME

[807.92(b)(1)] Determination of Substantial Equivalence

Non-Clinical Performance Data	The subject device did not undergo any design changes as a result of the proposed expanded indications. As a result, no additional non-clinical performance testing was required to demonstrate substantial equivalence.

[807.92(b)(2)] Determination of Substantial Equivalence

Clinical Performance Data	A clinical study was conducted in subjects with scarred, granulated or previously surgically altered tissue to support the proposed expanded indication. The subject device performed as intended and did not raise new safety concerns; there were no adverse events attributed to the subject device.

[807.92(b)(3)] Conclusion

Conclusions from Non-Clinical and Clinical Tests	The subject and predicate EM Sinus Dilation System devices are identical in design and performance specifications. Bench and animal testing was not required to demonstrate substantial equivalence. The proposed expanded indications were supported with a prospective, non-randomized, non-blinded, single arm, multicenter clinical study. Subjects with scarred, granulated or previously surgically altered tissue were enrolled and treated in at least one frontal, sphenoid, or maxillary sinus with the subject device. The subject device performed as intended and did not raise new safety concerns; there were no adverse events attributed to the subject device.