DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 22, 2015

Medtronic Xomed, Inc.
Ms. Michelle Hughes
Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, Florida 32216

Re: K151067
Trade/Device Name: Ventilation (Tympanostomy) Tubes
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: April 20, 2015
Received: April 21, 2015

Dear Ms. Hughes:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Ventilation (Tympanostomy) Tubes

Indications for Use *(Describe)*
Intended Use/ Indications for Use:

When inserted through a myringotomy, a ventilation tube provides a passageway for movement of air between the auditory canal and the middle ear. The unobstructed passageway may also allow a means of drainage of fluids resulting from acute or chronic otitis media from the middle ear into the auditory canal. In addition, surgical placement of ventilation tubes also provides a means of equalizing air pressures between the outer ear and the middle ear and continued ventilation to prevent fluid accumulation within the middle ear.

The surgeon must use medical judgment and consider the patient's medical history prior to a decision to surgically insert a ventilation tube. Pathologic conditions for which ventilation tubes are indicated include but not limited to:
• Chronic otitis media with effusion characterized as serous, mucoid, or purulent
• Recurrent acute otitis media which fails to respond satisfactorily to alternative therapies
• A patient with a history of persistent high negative middle ear pressure which may be associated with conductive hearing loss, otalgia, vertigo and/or tinnitus
• Atelectasis resulting from retraction pocket of the tympanic membrane or eustachian tube dysfunction

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

April 20, 2015

I. Company: Medtronic Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, Florida 32216 USA
Telephone Number: 904-332-2489
Fax Number: 904-296-2386

Contact: Michelle Hughes
Regulatory Affairs Specialist

Proprietary Trade Name: Ventilation (Tympanostomy) Tubes

II. Common Name: Tympanostomy Tubes

III. Classification Name: Tympanostomy Tubes (21 CFR 874.3880)

IV. Classification: Class II (21 CFR 874.3880)

V. Product Code: ETD

VI. Introduction:

Medtronic® Xomed®, Inc. is requesting clearance for Ventilation (Tympanostomy) Tubes that include both the 12 previously cleared premarket notifications and preamendment status devices. Medtronic® Xomed®, Inc. will use the 12 previously cleared premarket notifications as predicate devices.

VII. Product Description:

Medtronic® Xomed® Ventilation (tympanostomy) Tubes are small tubular implants available in a variety of biocompatible materials including silicone elastomer, fluoroplastic, C-FLEX® TPE, stainless steel and titanium. Numerous designs and sizes are available with single or multiple flanges to satisfy various surgical techniques for insertion and to facilitate short or long-term communication of the auditory canal with the middle ear. Some tubes are fitted with semi-permeable membranes intended to allow free passage of air while preventing movement of fluids into the middle ear.

VIII. Intended Use:

When inserted through a myringotomy, a ventilation tube provides a passageway for movement of air between the auditory canal and the middle ear. The unobstructed passageway may also allow a means of drainage of fluids resulting from acute or chronic

otitis media from the middle ear into the auditory canal. In addition, surgical placement of ventilation tubes also provides a means of equalizing air pressures between the outer ear and the middle ear and continued ventilation to prevent fluid accumulation within the middle ear.

IX. Indications for Use:

The surgeon must use medical judgment and consider the patient's medical history prior to a decision to surgically insert a ventilation tube. Pathologic conditions for which ventilation tubes are indicated include but not limited to:

- Chronic otitis media with effusion characterized as serous, mucoid, or purulent
- Recurrent acute otitis media which fails to respond satisfactorily to alternative therapies
- A patient with a history of persistent high negative middle ear pressure which may be associated with conductive hearing loss, otalgia, vertigo and/or tinnitus
- Atelectasis resulting from retraction pocket of the tympanic membrane or eustachian tube dysfunction

X. Identification of Legally Marketed Devices (Predicate Devices)

Ventilation (Tympanostomy) Tubes are substantially equivalent in intended use and performance characteristics to the following 12 previously cleared premarket notifications:

Description	510(k) Number	Clearance Date
Pope Umbrella Tube	K791680	11/13/1979
Otological Ventilation Tubes	K802587	11/12/1980
Tytan® Grommet Vent Tube, .040	K822366	09/02/1982
Armstrong V Vent Tube	K822375	09/09/1982
Grommet Vent Tube	K823908	01/28/1983
T-Tube Vent Tube	K823909	03/17/1983
Donaldson Vent Tubes	K823910	11/22/1983
Soileau Tytan Bobbin Vent Tube	K830584	06/02/1983
Ventilation Tubes w/ Hydrogel Coating	K923353	05/18/1993
C-Flex Vent Tubes	K943190	08/24/1994
Tympanostomy Tube	K955447	12/21/1995

Hoffman H/A Coated Long-Term Ventilation Tube with Liner	K963727	02/11/1997

XI. Comparison of the Technological Characteristics:

Feature	Subject Device	Predicates	Comparison
Product	Ventilation (Tympanostomy) Tubes	See Section IX	Same
510(k) Number	Proposed	See Section IX	Not Applicable
Product Code	ETD	ETD	Same
Classification	Class II	Class II	Same
Common Name/Classification Name	Tympanostomy Tubes	Tympanostomy Tubes	Same
Device Description	Medtronic® Xomed® Ventilation (tympanostomy) Tubes are small tubular implants available in a variety of biocompatible materials including silicone elastomer, fluoroplastic, C-FLEX® TPE, stainless steel and titanium. Numerous designs and sizes are available with single or multiple flanges to satisfy various surgical techniques for insertion and to facilitate short or long-term communication of the auditory canal with the middle ear. Some tubes are fitted with semi-permeable membranes intended to allow free passage of air while preventing movement of fluids into the middle ear.	Medtronic® Xomed® Ventilation (tympanostomy) Tubes are small tubular implants available in a variety of biocompatible materials including silicone elastomer, fluoroplastic, C-FLEX® TPE, stainless steel and titanium. Numerous designs and sizes are available with single or multiple flanges to satisfy various surgical techniques for insertion and to facilitate short or long-term communication of the auditory canal with the middle ear. Some tubes are fitted with semi-permeable membranes intended to allow free passage of air while preventing movement of fluids into the middle ear.	Same
Intended Use	When inserted through a myringotomy, a ventilation tube provides a passageway for movement of air between the auditory canal and the middle ear. The unobstructed passageway may also allow a means of drainage of fluids resulting from acute or chronic otitis media from the middle ear into the auditory canal. In addition, surgical placement of ventilation tubes also provides a	When inserted through a myringotomy, a ventilation tube provides a passageway for movement of air between the auditory canal and the middle ear. The unobstructed passageway may also allow a means of drainage of fluids resulting from acute or chronic otitis media from the middle ear into the auditory canal. In addition, surgical placement of ventilation tubes also provides a	Same

	means of equalizing air pressures between the outer ear and the middle ear and continued ventilation to prevent fluid accumulation within the middle ear.	means of equalizing air pressures between the outer ear and the middle ear and continued ventilation to prevent fluid accumulation within the middle ear.	
Indications for Use	The surgeon must use medical judgment and consider the patient's medical history prior to a decision to surgically insert a ventilation tube. Pathologic conditions for which ventilation tubes are indicated include but not limited to: • Chronic otitis media with effusion characterized as serous, mucoid, or purulent • Recurrent acute otitis media which fails to respond satisfactorily to alternative therapies • A patient with a history of persistent high negative middle ear pressure which may be associated with conductive hearing loss, otalgia, vertigo and/or tinnitus • Atelectasis resulting from retraction pocket of the tympanic membrane or eustachian tube dysfunction	The surgeon must use medical judgment and consider the patient's medical history prior to a decision to surgically insert a ventilation tube. Pathologic conditions for which ventilation tubes are indicated include but not limited to: • Chronic otitis media with effusion characterized as serous, mucoid, or purulent • Recurrent acute otitis media which fails to respond satisfactorily to alternative therapies • A patient with a history of persistent high negative middle ear pressure which may be associated with conductive hearing loss, otalgia, vertigo and/or tinnitus • Atelectasis resulting from retraction pocket of the tympanic membrane or eustachian tube dysfunction	Same
Technological Characteristics	Various Sizes (ID: 0.76-1.65; IFD: 1.09-9.80 L: 1.06-13.40 mm)	Various Sizes (ID: 0.76-1.65; IFD: 1.09-9.80 L: 1.06-13.40 mm)	Same

	Various Materials: Silicone, Teflon, Titanium Stainless Steel, C-Flex, Silicone/Microgel, FEP Fluoroplastic, Hydroxylapatite Coating	Various Materials: Silicone, Teflon, Titanium Stainless Steel, C-Flex, Silicone/Microgel, FEP Fluoroplastic, Hydroxylapatite Coating	
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Principle of Operation	Surgically inserted in the tympanic membrane following myringotomy to provide a passageway for the movement of air between the auditory canal and the middle ear	Surgically inserted in the tympanic membrane following myringotomy to provide a passageway for the movement of air between the auditory canal and the middle ear	Same

XII. Discussion of the Performance Testing

The Ventilation (Tympanostomy) Tubes did not undergo any design changes as a result of this submission. Therefore no additional bench, animal or clinical testing is required. A Literature Review is provided with post market surveillance data for these Ventilation Tubes.

XIII. Conclusions

A comparison of key characteristics demonstrates that the proposed submission consolidates previously cleared and preamendment Ventilation Tubes that have the same intended use/indications for use, technological characteristics and principle of operations. Based on this, Medtronic Xomed claims substantial equivalence to the predicate devices.