

OCT 31 2012

**510(k) SUMMARY  
SUMMARY OF SAFETY AND EFFECTIVENESS  
FOR**

**MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel**

<b>510(k) Owner</b>	Medtronic Xomed, Inc 6743 Southpoint Drive North Jacksonville, Florida 32216-0980 USA 904-296-9600 904-296-2386 (FAX)
<b>Contact Name</b>	Antoine Kouchakjy Principal Regulatory Affairs Specialist Medtronic Xomed, Inc
<b>Date Summary Prepared</b>	August 9, 2012
<b>Proprietary Name</b>	MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel
<b>Common Name</b>	Polymer, Ear, Nose and Throat, Synthetic, Absorbable
<b>Classification Name</b>	Ear, nose and throat synthetic polymer material (21 CFR 874.3620, Product Code NHB, Class II)

**Marketed device claiming equivalence to**

MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel (MeroGel) is equivalent to Medtronic Xomed's MeroGel Injectable Bioresorbable Stent, K070886.

**Device Description**

MeroGel is a sterile, transparent, viscoelastic, bioresorbable gel composed of cross-linked polymers of hyaluronic acid. The MeroGel device fills ENT cavities following surgery or trauma to keep tissues or structures separate during the healing process. During this time, the tamponade effect helps control minimal bleeding normally associated with routine ENT surgery. MeroGel leaves the site of placement by natural elimination, or it may be aspirated from the cavity earlier at the discretion of the physician.

**Intended Use**

MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel is a space occupying gel stent intended to separate and prevent adhesions between mucosal surfaces, help control minimal bleeding following surgery or nasal trauma, and act as an adjunct to aid in the natural healing process.

**Indications for Use**

MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery. The device is indicated following nasal / sinus surgery or trauma to prevent lateralization of the middle turbinate and nasal adhesions during the post operative period.

### **Summary of Changes**

- Manufacturing site change.
- Secondary sterilization method change
- Sterilization pouch material change.

### **Summary of Testing**

The following tests were conducted in order to demonstrate that the MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel is substantially equivalent to the MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel of K070886.

- Formulation for viscosity and HA concentration
- Filling process
- Terminal Sterilization processes (primary and secondary)
- Assembly
- Biocompatibility
- Labeling and Packaging

	MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel Medtronic Xomed 510(k) PROPOSED	MeroGel Injectable Bioresorbable Stent  Medtronic Xomed K070886
Device Name	ENT synthetic polymer material	ENT synthetic polymer material
Product Code	NHB	NHB
Intended Use / Indication	<p>Same as K070886:</p> <p>MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel is a space occupying gel stent intended to separate and prevent adhesions between mucosal surfaces, help control minimal bleeding following surgery or nasal trauma, and act as an adjunct to aid in the natural healing process.</p> <p>MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery. The device is indicated following nasal / sinus surgery or trauma to prevent lateralization of the middle turbinate and nasal adhesions during the post operative period.</p>	<p>MeroGel Injectable Bioresorbable Stent is a space occupying gel stent intended to separate and prevent adhesions between mucosal surfaces, help control minimal bleeding following surgery or nasal trauma, and act as an adjunct to aid in the natural healing process.</p> <p>MeroGel Injectable Bioresorbable Stent is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery. The device is indicated following nasal / sinus surgery or trauma to prevent lateralization of the middle turbinate and nasal adhesions during the post operative period.</p>
Material	Derivative hyaluronic acid	Derivative hyaluronic acid
Bioresorbable	YES	YES
Sterile	YES	YES
Product Matrix	Gel in a syringe	Gel in a syringe



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-002

OCT 31 2012

Medtronic Xomed, Inc.  
% Mr. Antoine Kouchakjy  
Principal Regulatory Affairs Specialist  
6743 Southpoint Drive North  
Jacksonville, FL 32216-0980

Re: K122434

Trade/Device Name: MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel

Regulation Number: 21 CFR 874.3620

Regulation Name: Ear, nose, and throat synthetic polymer material

Regulatory Class: Class II

Product Code: NHB

Dated: September 28, 2012

Received: October 1, 2012

Dear Mr. Kouchakjy:

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.

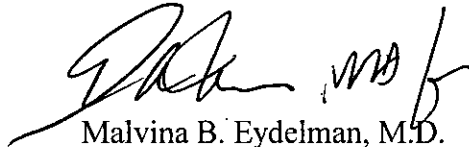
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "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,

A handwritten signature in black ink, appearing to read 'Malvina B. Eydelman', with a stylized flourish at the end.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,  
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): K122434

Device Name: MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel

**Indications For Use:**

MeroGel Injectable Bioresorbable Nasal Dressing and Sinus Stent and Otologic Gel is a space occupying gel stent intended to separate and prevent adhesions between mucosal surfaces, help control minimal bleeding following surgery or nasal trauma, and act as an adjunct to aid in the natural healing process.

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Prescription Use  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)

Daniel C Clapper  
(Division Sign-Off)  
Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

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