



Food and Drug Administration
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October 29, 2015

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

Re: K151758

Trade/Device Name: ALAR™ Nasal Valve Stent
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT, LYA
Dated: September 25, 2015
Received: October 1, 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

Malvina 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)

K151758

Device Name

ALAR™ Nasal Valve Stent

Indications for Use (Describe)

The ALAR™ Nasal Valve Stent is intended for use in supporting the lateral nasal wall during the post-operative healing period following nasal valve surgery. This procedure may be performed independently or in conjunction with other procedures such as septoplasty and turbinateplasty in order to address nasal obstruction.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K151758 - 510(k) Summary

- I. Submitter:** Medtronic Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, Florida 32216 USA
- Contact:** Gabriela Anchondo
Regulatory Affairs Manager
Telephone Number: 904-279-7550
Fax Number: 904-296-2386
- Date Summary Prepared:** June 24, 2015
- Trade Name:** ALAR™ Nasal Valve Stent
- II. Common Name:** Surgical Suture with Needle
Intranasal Splint
- III. Classification Name:** Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR 878.5000)
- IV. Classification:** Class II
- V. Predicate Devices:** K021019 Tevdek® Suture with Needle (GAT)
Class I Exempt Medtronic Xomed Internal Nasal Splints (LYA)
- VI. Device Description:** The elliptically shaped fluoroplastic stent is approximately 20 mm long and 16 mm wide. Slits symmetrically spaced along the stent's lateral edges allow for left and right nostril usage. The suture and needle attached to the stent provide stent anchoring and hold cartilage plates stable during post-operative healing.
- VII. Indications for Use:** The ALAR™ Nasal Valve Stent supports and immobilizes intranasal tissues and cartilage during the post-operative healing period following intranasal and nasal valve surgery.
- VIII. Technological Characteristics:** The ALAR™ Nasal Valve Stent system components have similar technological characteristics as the Medtronic Xomed Internal Nasal Stents and Tevdek® Suture with Needle including intended use, design, materials, principles of operation and performance.

IX. Discussion of the Performance Testing

Testing was completed to ensure the functionality and compatibility with the identified Medtronic Xomed products. Test samples were subjected to simulated real-life use conditions during functional testing. All function testing passed the test specifications and acceptance criteria for the bench top engineering studies. A biocompatibility assessment, sterility adoption, transportation and shelf life/aging testing was also conducted. Additional bench, animal or clinical testing was not required to establish substantial equivalence.

X. Conclusions

The indications for use, technology and performance characteristics of the ALAR™ Nasal Valve Stent system components are the same as the Medtronic Xomed Internal Nasal Splints and Tevdek® Suture with Needle. Based on this, Medtronic Xomed claims substantial equivalence to the predicate device.