*510(k) Number: K130354*

# 510(k) SUMMARY

**MAY 2 9 2013**

| | |
|---|---|
| **Date Prepared:** | May 28, 2013 |
| **Trade Name:** | MediENT® Middle Turbinate Implant |
| **Common Name:** | Intranasal splint |
| **Sponsor:** | ENTrigue Surgical, Inc.<br>12672 Silicon Drive, Suite 150<br>San Antonio, Texas 78249 USA<br>Telephone: 1-210-298-6336<br>Fax: 1-210-298-6399<br>Contact Person: Gabriele G. Niederauer, Ph.D. |
| **Product Code and Device Classification Name:** | LYA<br>Intranasal Splint (21 C.F.R. § 874.4780) |
| **Classification:** | Class I |
| **Predicate Devices:** | Walter Lorenz Surgical Inc., LactoSorb® Ethmoid Stent [K002131]<br>Medtronic Xomed Inc., MeroPack™ Nasal Packing and Sinus Stent [K041381] |
| **Intended Use/ Indications for Use:** | The MediENT® Middle Turbinate Implant is intended to separate the middle turbinate from the lateral nasal wall during the clinically relevant healing phase associated with nasal/sinus surgery. The implant provides short-term fixation of the middle turbinate to the nasal septum and thus minimizes the risk of adherence to the lateral nasal wall. |
| **Technological Characteristics:** | The MediENT® Middle Turbinate Implant is a tack made of an absorbable copolymer that is designed to hold the middle turbinate away from the lateral nasal wall. The sterile, single-use implant is delivered using standard surgical instruments, such as Alligator grasper, Pediatric Blakesly, MediENT® Grasper or similar. The implant provides temporary fixation and can be expected to start degrading approximately 2 to 3 months post-implantation. The MediENT® Middle Turbinate Implant is packaged and provided sterile for single use only. |

**Performance Data:**

Bench, cadaveric and clinical testing, using multiple users and study sites, was conducted to validate that the MediENT® Middle Turbinate Implant design met user requirements. Biocompatibility, sterilization, packaging, distribution, and shelf life testing were conducted in compliance with relevant standards. For clinical testing, a prospective, randomized, multi-center randomized trial was conducted at five U.S. centers and included 60 patients. Each subject was randomly treated with either MediENT® or the predicate MeroPack™. For up to 8 weeks, subjects were endoscopically examined to rate edema, infection and turbinate position and synechia was evaluated by a blinded reviewer. Clinical study results showed that MediENT was as good as MeroPack in preventing synechia and preventing lateralization of the middle turbinate. MediENT placement and implantation were safe and not associated with severe or significant adverse events. Results confirmed that the MediENT® Middle Turbinate Implant is substantial equivalent to the legally marketed predicate devices. In all instances, the MediENT® Middle Turbinate Implant functioned as intended.

**Substantial Equivalence:**

The MediENT® Middle Turbinate Implant is substantially equivalent to Medtronic Xomed's MeroPack™ Nasal Packing / Sinus Stent (K041381) and the Walter Lorenz Surgical's LactoSorb® Ethmoid Stent (K002131). The MediENT® Middle Turbinate Implant has the same intended uses and similar indications, technological characteristics (design, materials), and principles of operation as the predicate devices. The minor differences in technological characteristics or principles of operation between the MediENT® Middle Turbinate Implant and the predicate devices do not raise any new types of safety or effectiveness questions because the issues related to effective approximation of tissue for a sufficient period to allow for healing are common to each of these products. Performance data, including randomized clinical comparison testing in 60 patients, demonstrate that the MediENT® Middle Turbinate Implant is as safe and effective as the Medtronic Xomed's MeroPack™ Nasal Packing / Sinus Stent. Thus, the MediENT® Middle Turbinate Implant is substantially equivalent to the Medtronic Xomed's MeroPack™ Nasal Packing / Sinus Stent and the Walter Lorenz Surgical's LactoSorb® Ethmoid Stent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2013

ENTrigue Surgical, Inc.
Gabriele G. Niederauer, Ph.D.
Senior Vice President, Technology & Development
12672 Silicon Drive, Suite 150
San Antonio, TX 78249

Re: K130354
Trade/Device Name: MediENT® Middle Turbinate Implant
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: April 25, 2013
Received: April 26, 2013

Dear Dr. Niederauer:

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 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. 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,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K130354

Device Name: MediENT® Middle Turbinate Implant

Indications for Use:

The MediENT® Middle Turbinate Implant is intended to separate the middle turbinate from the lateral nasal wall during the clinically relevant healing phase associated with nasal/sinus surgery. The implant provides short-term fixation of the middle turbinate to the nasal septum and thus minimizes the risk of adherence to the lateral nasal wall.

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

Eric A. Mann -S

(Division Sign-Off)

Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K130354