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

April 13, 2015

Neoss, Ltd.
c/o Ms. Cherita James
M Squared Associates, Inc.
575 8th Avenue, Suite 1212
New York, NY 10018

Re: K143327
Trade/Device Name: Neoss Ti Reinforced Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPK
Dated: March 12, 2015
Received: March 13, 2015

Dear Ms. James:

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,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental 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)*

K143327

Device Name
Neoss Ti Reinforced Membrane

Indications for Use *(Describe)*

An implantable temporary non-resorbable device (membrane) for use as a spacer creation barrier in the treatment of local defects in the oral cavity in conjunction with tissue regeneration or augmentation. Neoss Ti Reinforced Membranes are intended to be submerged and clinically implanted more than 30 days with an expected duration of implantation up of 6 months.

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.**

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

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# 510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for the Neoss Ti Reinforced Membrane 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

**Sponsor:** Neoss Ltd
Windsor House
Cornwall Road
Harrogate, HG1 2PW, UK
Establishment Registration Number: 3005846524

**Contact:** Cherita James
M Squared Associates, Inc.
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E-mail: CJames@MSquaredAssociates.com

**Date of Submission: April 1, 2015**

**Proprietary Name: Neoss Ti Reinforced Membrane**

**Common Name**: Nonresorbable Barrier membrane

**Regulatory Class:** II

**Regulation:** 872.3930 Bone grafting material.

**Product Code:** NPK

**Predicate Device(s):** K960292 Gore-Tex Regenerative Material Ti Reinforced Configurations, K972278 Osteogenics Cytoplast Regentex Ti 250

**Device Description:** The Neoss Ti Reinforced Membrane a multi-layer non-resorbable dental membrane intended to be surgically placed beneath the muco-periosteum to aid in regenerative healing in 1) bone or 2) bone/periodontal ligament defects of the oral cavity. The Neoss Ti Reinforced Membrane is composed of two layers of PTFE membrane material enclosing a Titanium(Ti) mesh. The Neoss Ti Reinforced Membrane is a passive, non-load bearing material.

The small pores of the PTFE membrane material, allows passage of fluid and vapor; as well as a controlled cellular ingrowth for stability and a barrier for soft tissue penetration. The Ti mesh is unalloyed surgical grade Titanium ISO 5832-2 Grade 2. The titanium mesh reinforcement is

intended for space creating and shape-maintaining which minimizes movements and subsequent exposure while implanted. Neoss Ti Reinforced Membrane is provided pre-shaped in a variety of shapes and sizes detailed below. The device is supplied sterile and single use.

| Description/Image | Device Dimensions (mm) | Thickness (mm) |
|---|---|---|
| Neoss Ti Reinforced Membrane - S I | 28.7 x 18 | 0.3 |
| Neoss Ti Reinforced Membrane - M I | 30.4 x 19.4 | 0.3 |
| Neoss Ti Reinforced Membrane - L I | 35.9 x 21.2 | 0.3 |
| Neoss Ti Reinforced Membrane – M | 32.2 x 22 | 0.3 |
| Neoss Ti Reinforced Membrane - L | 34.2 x 24.8 | 0.3 |

**Indications for Use:** Neoss Ti Reinforced Membrane is an implantable temporary non-resorbable device (membrane) for use as a spacer creation barrier in the treatment of local defects in the oral cavity in conjunction with tissue regeneration or augmentation. Neoss membranes are intended to be submerged and clinically implanted more than 30 days with an expected duration of implantation up of 6 months.

Table 1. **Comparison to predicate devices**

| | **Neoss Ti Reinforced Membrane** | **Gore-Tex Regenerative Material Ti** | **Cytoplast Regentex Ti 250** | **Comment** |
|---|---|---|---|---|
| | Neoss LTD | W.L. Gore | Osteogenics | - |
| 510(k) No. | not yet assigned | K960292 | K972278 | - |
| Product Code | NPK | NPK | LYC | - |
| Indications for Use | An implantable temporary non-resorbable device (membrane) for use as a spacer creation barrier in the treatment of local defects in the oral cavity in conjunction with tissue regeneration or augmentation. Neoss membranes are intended to be submerged and clinically implanted more than 30 days with an expected duration of implantation up of 6 months. | intended to provide a mechanism for the ingrowth of new hard and soft tissues into bony defects surrounding teeth and to augment ingrowth of hard and soft tissues on alveolar ridges. | temporary implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal bone defects. | Substantially equivalent indications for use |

| | Neoss Ti Reinforced Membrane | Gore-Tex Regenerative Material Ti | Cytoplast Regentex Ti 250 | Comment |
|---|---|---|---|---|
| Design | 5 configurations, Ti mesh may be trimmed and shaped to create additional space for bone growth | "variety" of configurations and sizes | 8 configurations, Ti frame may be trimmed and shaped to create additional space for bone growth | Substantially equivalent design |
| Design | 5 configurations, Ti mesh may be trimmed and shaped to create additional space for bone growth | "variety" of configurations and sizes | 8 configurations, Ti frame may be trimmed and shaped to create additional space for bone growth | Substantially equivalent design |
| Material Composition | Non-resorbable Expanded and dense polytetrafluoroethylene (PTFE) and Titanium | Non-resorbable Expanded PTFE and Titanium | Non-resorbable High-Density PTFE and Titanium | Substantially equivalent materials |
| **Similar Specifications** | | | | |
| Thickness | 0.3 mm | 0.23 mm | 0.23 mm | Slightly greater thickness |
| Tensile strength | 0.5 bar for 60 sec | Unknown | Unknown | Performs as intended |
| Density (layer mass area g/dm2) | 3.5 | 2.8 | 4.0 | Substantially equivalent density |
| Biocompatible | Yes | Yes | Yes | Substantially equivalent |
| Sterility | EtO sterilized | sterile | sterile | Substantially equivalent |

**Technological Characteristics:** Neoss Ti Reinforced Membrane, like the predicate devices, is provided sterile. Both the subject and predicate devices are comprised of biocompatible non-resorbable PTFE and Titanium. The PTFE material of the Neoss device is similar in density (mass/area) and thickness to both of the predicate devices.

In the subject device, the Neoss device has a single monodirectional dense PTFE layer and expanded multi-directional layers. The dense surface is intended to be placed towards the soft tissue, while the expanded surface is intended to be placed towards the defect and bone. The Gore predicate device is comprised of an expanded PTFE, while the Cytoplast is composed of dense

PTFE. Both membrane materials in the Neoss membrane are less dense than the Cytoplast membrane but not as expanded as the Gore membrane. The dense material of the Neoss membrane is similar to the Cytoplast membrane and serves to provide a semi-closed structured surface to facilitate cellular adhesion while providing a barrier function so that only desirable cells can be developed and thereby allowing regeneration to occur by excluding epithelial cell penetration through the barrier. The more expanded material of the Neoss multilayer membrane configuration offers similar strength to the membrane as the Gore product and additional microporosity for cellular attachment providing stability if the membrane during clinical function.

**Performance Testing:** The Neoss Ti Reinforced Membrane was evaluated for Burst Strength and Bend Testing in order to confirm the strength, integrity and functionality of the device. The subject device and processes were also tested according to the following standards:

- ISO 5832-2:1999 Implants for surgery -- Metallic materials -- Part 2: Unalloyed titanium
- ISO 10993-5 Biological Evaluation Of Medical Devices: Test for in vitro cytotoxicity
- ISO 10993-7 Biological Evaluation Of Medical Devices: Ethylene Oxide Sterilization Residuals
- ISO 10993-10 Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization
- ISO 10993-18 Biological Evaluation Of Medical Devices: Chemical Characterization of Material
- ISO 11135-1 Sterilization of health care products – Ethylene Oxide
- BS EN 868-5:2009 Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods
- ASTM F1980-07:2011 Standard Guide for Accelerated aging of Sterile Barrier Systems for Medical Devices
- ASTM F1140-07 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.
- ASTM F1929-12 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration-Method A.

**Clinical Testing:** Clinical data was not required to establish the substantial equivalence of the Neoss Ti Reinforced Membrane.

**Conclusion:** The Neoss Ti Reinforced Membrane is similar to legally marketed devices listed previously in that they share similar indications for use and incorporate similar technological

characteristics. All evaluations determined that the Neoss Ti Reinforced Membrane is substantially equivalent to the predicate devices.