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

November 19,2015

Unicare Biomedical, Inc.
Stan Yang
Vice President
23011 Moulton Parkway, J-11
Laguna Hills, California 92653

Re: K151344
Trade/Device Name: Cytoflex Tefguard Ti-enforced Eptfe Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPK
Dated: October 14, 2015
Received: October 19, 2015

Dear Stan Yang:

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,

Erin Keith
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.

10(k) Number *(if known)*
K151344

Device Name
Cytoflex® Tefguard® Ti-Enforced membrane

Indications for Use *(Describe)*
Cytoflex® Tefguard® Ti-Enforced membrane is a temporarily, non-resorbable, implantable material for use as a space-making barrier in the treatment of periodontal defects and augmentation of alveolar ridge in accordance with guided tissue regeneration principle.

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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SECTION 6

510(K) SUMMARY

510(k) Summary K151344

(As Required by 21CFR 807.92 (c))

1. Submitter

Name:	Unicare Biomedical
Address:	23011 Moulton Parkway, J-11, Laguna Hills, California 92653 USA
Tel:	Tel: 949-305-1770; Fax: 949-334-1338
Contact:	Stan Yang, PhD
Date:	June 15, 2015

2. Trade/Device Name: Cytoflex® Tef-Guard® Ti-Enforced Membrane
   Common Name: Non-resorbable barrier membrane
   Regulation Number: 21 CFR 872.3930
   Regulation Name: Barrier, Synthetic, Intraoral
   Regulation Class: II
   Product Code: NPK

3. Predicate Devices

   Primary predicate device -

   Cytoplast® Titanium reinforced high density PTFE membranes (K972278; Osteogenics Biomedical, Inc.)

   Reference predicate device -

   Neoss Ti Reinforced Membrane (K143327; Neoss Ltd)

4. Device Description

   Cytoflex® Tef-Guard® Ti-Enforced membranes are a multi-layer, non-resorbable membrane intended to be surgically placed under the muco-periosteum to aid in tissue regeneration in accordance with the guided tissue regeneration principle. It is a passive, non-load bearing material with a titanium frame enclosed within two exterior layers of ePTFE material. The titanium reinforcement is intended for space and shape maintenance to contain bone grafting material and to minimize graft migration during wound healing. The membranes are designed to reduce the migration and establishment of gingival tissue derived cells into bony defects thus providing a more

favorable environment for neovascularization and bone derived cells to repopulate and repair the defect. The membranes are intended to be submerged and implanted for more than 30 days and up to 6 months. The membrane is supplied sterile and available in a variety of shapes and sizes for single use only.

Description / Model	Dimension	Thickness
Cytoflex® Tef-Guard® Ti-Enforced membrane / T-001	11x21mm	0.25mm
Cytoflex® Tef-Guard® Ti-Enforced membrane / T-002	19x26mm	0.25mm
Cytoflex® Tef-Guard® Ti-Enforced membrane / T-003	23x29mm	0.25mm
Cytoflex® Tef-Guard® Ti-Enforced membrane / T-004	32x40mm	0.25mm

5. Indication

Cytoflex® Tef-Guard® Ti-Enforced membrane is a temporarily, non-resorbable, implantable material for use as a space-making barrier in the treatment of periodontal defects and augmentation of alveolar ridge in accordance with guided tissue regeneration principle.

6. Comparison with Primary Predicate Device and Reference Predicate Device

Device Name / Comments	Cytoflex Tef-Guard Ti-Enforced Membrane	Cytoplast Titanium Reinforced high density PTFE Membrane*	Neoss Ti Reinforced Membrane**	Comments
510K ID	K 151344	K 972278	K 143327	-
Indications for use	Temporarily implantable material (non-resorbable) for use as a space-making barrier in the	Temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment	An implantable temporary non-resorbable membrane for use as a spacer creation barrier in the treatment	Substantially Equivalent indications for use

	treatment of periodontal defects and alveolar ridge augmentation	of periodontal defects	of local oral defects in conjunction with tissue regeneration or augmentation.	
Implant sites	periodontal defects & alveolar ridge	periodontal defects	Oral bony cavity	Substantially equivalent implant sites
Design	A variety of configurations. May be trimmed and shaped to fit bony defect.	A variety of configurations. May be trimmed and shaped to fit bony defect.	A variety of configurations. May be trimmed and shaped to fit bony defect.	Substantially equivalent design
Material	ePTFE membranes reinforced with a Titanium frame	High density PTFE membranes reinforced with a Titanium frame	ePTFE and dense PTFE membranes reinforced with a Titanium frame	Substantially Equivalent material
Thickness	0.25mm	0.23mm	0.3mm	Substantially Equivalent
Density	3.5 g/dm^2	4.0 g/dm^2	3.5 g/dm^2	Substantially Equivalent
Biocompatible	Yes	Yes	Yes	Substantially Equivalent
Sterility	Sterile by EtO gas, SAL $\leq 10^{-6}$	Sterile	Sterile	Substantially Equivalent

*Primary Predicate Device; ** Reference Predicate Device

7. Device Characteristics

As summarized in the comparison Table above, the designs of Cytoflex® Tef-Guard® Ti-Enforced membranes are substantially equivalent to the primary predicate device, Cytoplast Titanium Reinforced high density PTFE Membrane, and reference predicate device, Neoss Ti Reinforced Membrane. The subject and the predicate devices are passive, non-load bearing membranes for use to maintain space and shape to contain bone grafting material and to minimize graft migration during wound healing. The membranes are designed to reduce the migration and establishment of gingival tissue derived cells

into bony defects thus providing a more favorable environment for neovascularization and bone derived cells to repopulate and repair the defect in accordance with the guided tissue regeneration principle to repair periodontal defects and/or augment alveolar ridge. The devices are for single use only and are provided sterile with a variety of configurations for different bony size defects.

8. Performance Testing

   The performance of Cytoflex® Tef-Guard® Ti-Enforced membrane was evaluated against the primary predicate device for tensile loading, bending loading, flexibility and delaminating potential. The test results demonstrate that the subject device is substantially equivalent to the primary predicate device in functional performance.

   Cytoflex® Tef-Guard® Ti-Enforced membrane is made of substantially equivalent biocompatible materials as the predicate devices. The subject device was tested according to the following ISO standards, and was found to meet the requirements of the pre-defined acceptance criteria. The results of the above testing demonstrate that the Cytoflex® Tef-Guard® Ti-Enforced membrane is substantially equivalent in safety and effectiveness, and its performance meets the requirements of its pre-defined acceptance criteria and intended use.

   - ISO 11135 (2014) - Sterilization of health-care products - Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
   - ISO 10993-5 (2009) - Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity
   - ISO 10993-6 (2007) - Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
   - ISO 10993-10 (2010) - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
   - ISO 10993-11 (2006) - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity in Mice

- ISO 10993-11 (2006) - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity in Rats following subcutaneous implantation, 4 weeks
- ISO 10993-7 (2008R2012) - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

9. Clinical Testing

   Clinical data was not required to establish the substantial equivalence of the Cytoflex® Tef-Guard® Ti-Enforced Membrane.

10. Conclusion

    Cytoflex® Tef-Guard® Ti-Enforced Membranes are substantially equivalent to the primary predicate device in that they have similar indications for use and exhibit substantially equivalent technology and device characteristics, including thickness, dimension, density, design and material composition when compared with the predicate devices. The test results demonstrate that Cytoflex® Tef-Guard® Ti-Enforced Membranes are biocompatible and perform substantially equivalent to the primary predicate device.