January 23, 2021

Osteogenics Biomedical, Inc.
Shane Shuttlesworth
President
4620 71st St., Bldg. 78
Lubbock, Texas 79424

Re: K201187
Trade/Device Name: Cytoplast™ Titanium-Reinforced PTFE Membranes
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPK
Dated: December 28, 2020
Received: December 28, 2020

Dear Shane Shuttlesworth:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201187

Device Name
Cytoplast™ Titanium-Reinforced PTFE Membranes

Indications for Use *(Describe)*
Cytoplast™ Titanium-Reinforced PTFE Membranes are a temporarily implantable material (non- resorbable) indicated for use as a space-making barrier in the treatment of alveolar and periodontal bony defect sites.

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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K201187

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

Applicant Name:	Osteogenics Biomedical, Inc.
Address:	4620 71st St, Bldg. 78 Lubbock, Texas 79424
Phone:	(806) 796-1923
Fax:	(806) 796-0059
Contact Person:	Shane Shuttlesworth President
Date Prepared:	January 22, 2021

II. DEVICE

Trade Name:	Cytoplast™ Titanium-Reinforced PTFE Membranes
Common Name:	PTFE Membrane
Regulation Name:	Bone Grafting Material
Regulation Number:	21 CFR 872.3930
Regulatory Class:	II
Product Code:	NPK (Barrier, Synthetic, Intraoral)

III. PRIMARY PREDICATE DEVICE

Primary Predicate Device:	Cytoplast™ Regentex™ Titanium 250 (Osteogenics Biomedical, Inc.) K972278

RPM™ Reinforced PTFE Mesh (K171774) and Bio-Gide® Resorbable Bilayer Membrane (K050466) were used as a reference devices in this submission.

IV. DEVICE DESCRIPTION

Cytoplast™ Titanium-Reinforced PTFE Membranes are placed between bone grafts and the periosteum in dental bone grafting procedures to stabilize and support the bone graft. The PTFE membrane helps create the space needed for bone-derived cells to repopulate and repair the defect.

Cytoplast™ Titanium-Reinforced PTFE Membranes are composed of proprietary 100% polytetrafluoroethylene sheets reinforced with a titanium frame. The titanium frame is embedded between two layers of PTFE. PTFE is biologically nearly inert and a tissue-compatible material.

The PTFE membranes are designed to maintain space and conform to tissue contours.

Cytoplast™ Titanium-Reinforced PTFE Membranes are provided in two different thicknesses (approximately 150 µm & 250 µm) and are pre-shaped in a variety of shapes and sizes. Outer dimensions include:

- 12 mm x 20 mm
- 12 mm x 24 mm
- 12 mm x 30 mm
- 13 mm x 18 mm
- 13 mm x 19 mm
- 14 mm x 24 mm
- 17 mm x 25 mm
- 20 mm x 25 mm
- 24 mm x 38 mm
- 25 mm x 36 mm
- 25 mm x 30 mm
- 30 mm x 41 mm
- 30 mm x 40 mm
- 38 mm x 38 mm
- 40 mm x 50 mm

V. INDICATIONS FOR USE

Cytoplast™ Titanium-Reinforced PTFE Membranes are a temporarily implantable material (non-resorbable) indicated for use as a space-making barrier in the treatment of alveolar and periodontal bony defect sites.

VI. COMPARISON OF INDICATIONS FOR USE WITH THE PRIMARY PREDICATE DEVICE

The term “alveolar defects” has been added to the indication for use for the subject device. The term “alveolar defects” includes any bony defect found within the alveolus, both in the mandible and the maxilla. Using the term alveolar defects focuses the indication on the location of the defect rather than the etiology of bone loss and still aligns with how the devices are being used clinically.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Cytoplast™ Titanium-Reinforced PTFE Membranes are substantially equivalent to the primary predicate device, Cytoplast™ Regentex™ Titanium 250. Cytoplast™ Titanium-Reinforced PTFE Membranes are identical in design, function, composition, biocompatibility, sterilization, sizes, packaging, shelf life, physical properties, and intended use to the legally marketed primary predicate device, Cytoplast™ Regentex™ Titanium 250. See comparison table below:

	Cytoplast™ Titanium-Reinforced PTFE Membranes (K201187) Osteogenics Biomedical, Inc.	**Cytoplast™ Regentex™ Titanium 250** (K972278) Osteogenics Biomedical, Inc.	**RPM™ Reinforced PTFE Mesh** (K171774) Osteogenics Biomedical, Inc.	**Bio-Gide® Resorbable Bilayer Membrane** (K050466) Geistlich, Pharma
Product Code	NPK	LYC	NPK	NPL
Indications for Use	A temporarily implantable material (non-resorbable) indicated for use as a space-making barrier in the treatment of alveolar and periodontal bony defect sites. Rx Only	A temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects. Rx Only	For stabilization and support of bone grafts in alveolar bony defect sites. Rx Only	Simultaneous use of GBR-membrane and implants; augmentation around implants placed in immediate extraction sockets; augmentation around implants placed in delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects after root resection, cystectomy, removal of retained teeth; guided bone regeneration in dehiscence defects; guided tissue regeneration procedures in periodontal defects. Rx Only
Operational Principles	Cytoplast™ Titanium-Reinforced PTFE Membranes are placed between bone grafts and the periosteum in dental bone grafting procedures to stabilize and	Cytoplast™ Regentex™ Titanium 250 is placed between bone grafts and the periosteum in dental bone grafting procedures to stabilize and support the bone	RPM™ Reinforced PTFE Mesh is placed between bone grafts and the periosteum in dental bone grafting procedures to stabilize and support the bone graft. The PTFE	BIO-GIDE® resorbable bilayer membrane is for guided tissue and bone regeneration.

	support the bone graft. The PTFE membrane isolates the space needed for bone-derived cells to repopulate and repair the defect.	graft. The PTFE membrane isolates the space needed for bone-derived cells to repopulate and repair the defect.	mesh helps create the space needed for bone-derived cells to repopulate and repair the defect.	
Design	Titanium frame embedded between two layers of PTFE. Titanium frame may be trimmed and shaped to create additional space for bone growth.	Titanium frame embedded between two layers of PTFE. Titanium frame may be trimmed and shaped to create additional space for bone growth.	Titanium frame embedded between two layers of PTFE. Titanium frame may be trimmed and shaped to create additional space for bone growth. Macropores allow direct contact between the bone graft and the periosteum. Direct contact between the periosteum and bone graft allows naturally occurring revascularization and infiltration of cells.	Resorbable bilayer membrane composed of collagen type I and type III without further cross-linking or chemical treatment. The porous surface - facing the bone - allows the ingrowth of bone forming cells. The dense surface - facing the soft tissue - prevents the ingrowth of fibrous tissue into the bone defect.
Composition	100% PTFE, Titanium	100% PTFE, Titanium	100% PTFE, Titanium	Type I and Type III Collagen
Use	Single	Single	Single	Single
Shelf Life	4 years	4 years	4 years	Unknown
Biocompatible	Yes	Yes	Yes	Yes
Sterilization	Sterile	Sterile	Sterile	Sterile
Model Sizes	Various	Various	Various	Various
Maximum Duration of Implantation	12 months	Not Stated	12 months	Unknown

RPM™ Reinforced PTFE Mesh is being used as a reference device to leverage biocompatibility testing performed on this device as applicable to the subject device, Cytoplast™ Titanium-Reinforced PTFE Membranes, since these devices are identical for the purposes of these tests.

The tensile specification for the Cytoplast™ Titanium-Reinforced PTFE Membranes has been selected based off of the reference device, Bio-Guide® Resorbable Bilayer Membrane.

VIII. PERFORMANCE DATA

Nonclinical Tests Submitted

The substantial equivalence of Cytoplast™ Titanium-Reinforced PTFE Membranes and its primary predicate was demonstrated based on *in vitro* characterization studies.

Non-clinical testing was performed in accordance with FDA recognized consensus standards and FDA guidelines as applicable.

A complete biocompatibility risk assessment conducted in accordance with ISO series 10993-1 demonstrated biocompatibility risks were able to be mitigated by leveraging biocompatibility testing for the reference device as they are composed of identical materials, manufacturing processes, sterilization and packaging. Biocompatibility of the subject device was confirmed with ISO 10993 testing as follows:

- Cytotoxicity: ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells
- Irritation (including Intracutaneous reactivity)
- Toxicity (acute, subacute, subchronic, chronic)
- Implantation

Sterilization validation for Ethylene Oxide was performed per ISO 11135-1:2007 to achieve a Sterility Assurance Level of 10^{-6}. Shelf-life testing was performed in compliance with ISO 11607-1.

In vitro product characterization testing was performed to demonstrate substantial equivalence of the subject device to its primary predicate and reference devices. A series of bench tests were conducted to evaluate material and physical properties.

Tensile strength was characterized and compared to the reference device, Bio-Gide® Resorbable Bilayer Membrane, in order to establish a minimum acceptable specification. Lamination was characterized to ensure it is appropriate for the clinical application of the membranes. The comparative bench testing is summarized in the table below.

Test	Test Method	Results
Tensile Strength	ASTM D638-14	Tensile strength ≥ reference device
Lamination Strength	Internal	Lamination is acceptable

IX. CONCLUSION

The results of *in vitro* device characterization tests show that the subject device, Cytoplast™ Titanium-Reinforced PTFE Membranes, is substantially equivalent to the primary predicate and reference devices. ISO 10993 testing confirms the biocompatibility of the subject device. Tensile strength testing shows that the subject device is at least as strong as the reference device, Bio-Gide®. Lamination tests show that the subject device is acceptable for its clinical application.