Osteogenics Biomedical, Inc.
Shane Shuttlesworth
President
4620 71st St. Bldg. 78-79
Lubbock, Texas 79424

October 19, 2017

Re: K171774
Trade/Device Name: RPM Reinforced PTFE Mesh
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPK
Dated: June 14, 2017
Received: June 14, 2017

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. 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 (DICE) 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 (DICE) 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,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting 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)*
K171774

Device Name
RPM™ Reinforced PTFE Mesh

Indications for Use *(Describe)*
RPM™ Reinforced PTFE Mesh is a temporarily implantable material (non-resorbable) indicated for stabilization and support of bone grafts in alveolar 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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:	May 10, 2017

II. DEVICE

Trade Name:	RPM™ Reinforced PTFE Mesh
Common Name:	PTFE Mesh
Regulation Number:	21 CFR 872.3930
Regulation Name:	Bone Grafting Material
Regulatory Class:	II
Product Code:	NPK (Barrier, Synthetic, Intraoral)

III. PREDICATE DEVICE

Predicate Device:	Osteo-Mesh™ TM-300 (Osteogenics Biomedical, Inc.) K984230

Cytoplast™ Regentex™ Titanium 250 (K972278) and Bio-Gide® Resorbable Bilayer Membrane (K050466) were used as a reference devices in this submission.

IV. DEVICE DESCRIPTION

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 mesh helps create the space needed for bone-derived cells to repopulate and repair the defect.

RPM™ Reinforced PTFE Mesh is composed of proprietary 100% polytetrafluoroethylene sheets reinforced with a titanium frame. The titanium frame is embedded between two layers of PTFE. PTFE is a biologically inert and tissue-compatible material. RPM™ Reinforced PTFE Mesh is manufactured with circular 0.66 mm diameter macropores to 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.

The PTFE mesh is designed to maintain space and conform to tissue contours.

RPM™ Reinforced PTFE Mesh is provided pre-shaped in a variety of shapes and sizes. Outer dimensions include:

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

V. INDICATIONS FOR USE

RPM™ Reinforced PTFE Mesh is a temporarily implantable material (non-resorbable) indicated for stabilization and support of bone grafts in alveolar bony defect sites.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

RPM™ Reinforced PTFE Mesh is substantially equivalent to the predicate device, Osteo-Mesh™ TM-300, and the reference device, Cytoplast™ Regentex™ Titanium 250. RPM™ Reinforced PTFE Mesh is identical in design, function, and intended use to the legally marketed predicate device Osteo-Mesh™ TM-300. RPM™ Reinforced PTFE Mesh is identical in composition, biocompatibility, sterilization, model sizes, packaging, shelf life, physical properties, and intended use to the legally marketed reference device Cytoplast™ Regentex™ Titanium 250. See comparison table below:

	RPM™ Reinforced PTFE Mesh Osteogenics Biomedical, Inc.	**Osteo-Mesh™ TM-300** (K984230) Osteogenics Biomedical, Inc.	**Cytoplast™ Regentex™ Titanium 250** (K972278) Osteogenics Biomedical, Inc.
Product Code	NPK	LEY	LYC
Indications for Use	For stabilization and support of bone grafts in alveolar bony defect sites. Rx Only	For stabilization and support of bone grafts in dento-alveolar 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
Operational Principles	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 mesh helps create the space needed for bone-derived cells to repopulate and repair the defect.	Osteo-Mesh™ TM-300 is placed between bone grafts and the periosteum in dental bone grafting procedures to stabilize and support the bone graft. The PTFE mesh helps create the space needed for bone-derived cells to repopulate and repair the defect.	Cytoplast™ Regentex™ Titanium 250 is placed between bone grafts and the periosteum in dental bone grafting procedures to stabilize and support the bone graft. The PTFE mesh isolates 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. 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.	Titanium mesh 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.	Titanium frame embedded between two layers of PTFE. Titanium frame may be trimmed and shaped to create additional space for bone growth.
Composition	100% PTFE, Titanium	Titanium	100% PTFE, Titanium
Pores	Macro	Macro	Micro
Use	Single	Single	Single
Shelf Life	4 years	N/A	4 years
Biocompatible	Yes	Yes	Yes
Sterilization	Sterile	Non-Sterile	Sterile
Model Sizes	Various	Various	Various
Maximum Duration of Implantation	12 months	Not Stated	Not Stated

VII. PERFORMANCE DATA

Nonclinical Tests Submitted

The substantial equivalence of RPM™ Reinforced PTFE Mesh and its predicate was demonstrated based on *in vitro* characterization studies, biocompatibility studies, and clinical history of the reference devices.

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

In vitro product characterization testing was performed to demonstrate substantial equivalence of the subject device to its reference devices. A series of bench tests were conducted to evaluate material properties, biological properties, chemical 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 strength and suture retention force were characterized and compared to the reference device, Cytoplast™ Regentex™ Titanium 250.

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 strength ≥ reference device
Suture Retention Force	Internal	Suture retention force ≥ reference device

In vitro biocompatibility testing was performed to assess biocompatibility of the RPM™ Reinforced PTFE Mesh as an implantable material.

The subject device passed the following FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

Test	**Test Method/Model**	**Results**
Cytotoxicity	ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells, ISO 10993-5	Non-cytotoxic
Irritation	Oral Mucosa Irritation, ISO 10993-10	Non-irritant

VIII. CONCLUSION

The results of *in vitro* device characterization tests show that the subject device, RPM™ Reinforced PTFE Mesh, is substantially equivalent to the predicate device or reference devices. Tensile strength testing shows that the subject device is at least as strong, statistically, as the reference device, Bio-Gide®. Lamination strength and suture retention force tests show that the subject device is at least as strong, statistically, as the reference device, Cytoplast™ Regentex™ Titanium 250. Biocompatibility testing demonstrated that the subject device is non-cytotoxic and a non-irritant.