December 08, 2023

Criteria Industria e Comercio de Produtos Medicinais
% Graziela Brum
Regulatory Affairs Specialist
PR Servicos Regulatorios Administrativos Ltda
Rua Alice Alem Saadi, 855, 2402
Ribeirao Preto, SP 14096570
BRAZIL

Re: K221851
Trade/Device Name: Lumina-PTFE Titanium
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: Class II
Product Code: NPK
Dated: December 5, 2023
Received: December 5, 2023

Dear Graziela Brum:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221851

Device Name
Lumina-PTFE Titanium

Indications for Use *(Describe)*
Lumina-PTFE Titanium is 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.

Lumina-PTFE Titanium

510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	Critéria Indústria e Comércio de Produtos Medicinais e Ondontológicos LTDA Alameda Sinlioku Tanaka, 170, Galpão 44- Parque Technologico Damha I São Carlos, SP - Brazil
Contact Person and Prepare	Graziela Brum and Tatiana Jabor Botura Regulatory Affairs Specialist Passarini Regulatory Affairs e-mail: graziela@passarini.com.br Telephone: +55 (16) 3421 8488
Data Prepared	December 5, 2023

DEVICE NAME AND CLASSIFICATION

Trade Name	Lumina-PTFE Titanium
Common Name	PTFE Membrane
Regulation Number	21 CFR 872.3930
Regulatory Class	II
Product Code	NPK
Classification Panel	Dental

PREDICATE DEVICE INFORMATION

Primary Predicate Manufacture	Osteogenics Biomedical, Inc.

Predicate Trade Name	Cytoplast™ Titanium-Reinforced PTFE Membranes
Predicate 510 (K)	K201187

Indications For Use

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

Subject Device Description

Lumina-PTFE Titanium is a synthetic, biocompatible, single-use, sterile polymeric barrier composed of a 100% polytetrafluoroethylene (PTFE) reinforced by a titanium structure. The titanium frame is embedded between two layers of PTFE.

This medical device is 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.

The PTFE membranes are designed to maintain space and conform to tissue contours. Lumina-PTFE Titanium is provided in thicknesses of 0,25mm and different sizes, the dimensions include:

- 10mm x 25mm
- 14mm x 24mm
- 20mm x 25mm
- 20mm x 30mm
- 17mm x 25mm
- 25mm x 30mm
- 24mm x 38mm
- 38mm x 38mm

Technological Characteristics

Table 5.1 Compare between Lumina-PTFE Titanium and Cytoplast™ Titanium- Reinforced PTFE.

	Subject Device	Predicate Device
	Lumina-PTFE Titanium	Cytoplast™ Titanium- Reinforced PTFE Membranes (K201187)
Product Code	NPK	NPK
Indications for use	Lumina-PTFE Titanium is a temporarily implantable material (non-resorbable) indicated for use as a space-making barrier in the treatment of alveolar and periodontal bony defect sites.	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.
Principle of Operation	Lumina PTFE-Titanium are placed between bone grafts and the periosteum in dental bone grafting procedures to stabilize and support the bone graft. The PTFE membrane isolates the space needed for bone-derived cells to repopulate and repair the defect.	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 isolates the space needed for bone-derived cells to repopulate and repair the defect.
Design	Lumina PTFE Titanium polymeric barrier with titanium structure embedded between two layers of PTFE.	Titanium frame embedded between two layers of PTFE.
Composition	Lumina PTFE-Titanium are composed of proprietary 100% polytetrafluoroethylene sheets reinforced with a titanium frame.	Cytoplast™ Titanium-reinforced PTFE Membranes are composed of proprietary 100% polytetrafluoroethylene sheets reinforced with a titanium frame.
Use	Single use	Single use

Shelf Life	2 years	4 years
Biocompatible	Yes	Yes
Sterilization	Sterile/Ethylene Oxide	Sterile/Ethylene Oxide
Model Sizes*	10mm x 25mm 14mm x 24mm 20mm x 25mm 20mm x 30mm 17mm x 25mm 25mm x 30mm 24mm x 38mm 38mm x 38mm	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
Maximum Duration of Implantation	12 months	12 months

*Except for the 10mm x 25mm and 20mm x 30mm size models, all others have the same dimensions as the equivalent product. Despite the small difference present in the two previously mentioned models, the total area of the membrane is similar to the predicate. These small differences in size did not have a clinical effect on the product, because the surgeon chooses the size that best fits the patient's bone defect. In addition, to adjust the size of the bone defect, the surgeon can cut the membrane, as instructed in the instructions for use.

The subject and predicate devices have similar intended use and principles of operation, dimensions, and technological characteristics.

The Lumina-PTFE Titanium composition is the same as the one used for the fabrication of the predicate device K201187.

Biocompatibility of the subject device materials was supported by the following tests: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Genotoxicity, Hemocompatibility, Implantation and Subchronic Systemic Toxicity according to the FDA guidance entitled Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", dated on September 4, 2020.

Sterilization validation for Ethylene Oxide was performed per ISO 11135-1 to achieve a Sterility Assurance Level of 10^{-6}. Shelf-life testing was performed in compliance with ASTM 1980.

The absorption test shows that Lumina-PTFE Titanium presented an absorption rate compatible with the predicate device, thereby it is a non-absorbable membrane.

A wettability test (contact angle) was conducted and demonstrated that the Lumina-PTFE Titanium has a contact angle equivalent with the predicate device.

The tension break and elasticity results demonstrated that the subject device when tested in comparison with the predicate device showed equivalent outcomes.

The Suture Pullout Strength and Peel Resistance results demonstrated that the subject device when tested in comparison with the predicate device showed equivalent outcomes. Although the products have different adhesion methods, Peel Resistance test in accordance with ASTM D 1876-8 have shown that the products have equivalent results.

In conclusion, the Lumina-PTFE Titanium is substantially equivalent to the Cytoplast™ Titanium-Reinforced PTFE Membranes.

Non-Clinical Performance Data:

Lumina-PTFE Titanium was tested following these standards:

- ASTM D638-14 Standard Test Method for Tensile Properties of Plastics
- ISO 5832-2 Implants for surgery – Metallic materials – Part 2: Unalloyed titanium
- ASTM F754-08 Standard Specification for Implantable PTFE Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders.
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier System for Medical Devices
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ASTM D 1876-08 Standard Teste Method for Peel Resistance of Adhesives

Clinical performance Data:

No clinical data were included in this submission.

Conclusion:

The documentation submitted in this premarket notification demonstrates that the subject devices have comparable features and performance and, therefore, are substantially equivalent to the identified predicate device.