July 6, 2026

GC America, Inc.
Futoshi Fusejima
Director of Product Engineering and Regulatory Affairs
3737 W 127th St.
Alsip, Illinois 60803

Re: K253317
Trade/Device Name: Cytrans™ Elashield
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: LYC
Dated: June 5, 2026
Received: June 5, 2026

Dear Futoshi Fusejima:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253317

Device Name
Cytrans™ Elashield

Indications for Use *(Describe)*
Cytrans™ Elashield is intended for the following uses as a space-making barrier:

- Guided bone regeneration in oral surgery
- Alveolar ridge augmentation
- Guided tissue regeneration in periodontal defects
- Extraction socket site preservation
- Sinus lifts
- Immediate implant placement at time of extraction or delayed placement
- Treatment of associated cystic defect
- The containment of bone grafting materials

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

K253317

1. Submitter Information:

GC America Inc.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Futoshi Fusejima.
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Alternate Contact: John Oberholtzer
Phone: (708) 926-3246
Fax: (708) 925-0373

Date Prepared: June 30, 2026

2. Device Name:

Proprietary Name: Cytrans™ Elashield
Common Name: Resorbable barrier membrane
Classification Name: Bone Grafting Material, Synthetic
Device Classification: Class II, 872.3930
Product Code: LYC

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No	Predicate	Decision Date
CytoFlex® Resorb	UNICARE BIO-MEDICAL, INC.	K090083	LYC	Primary	03/23/2009
Geistlich Bio-Gide®	Geistlich Pharma AG	K212463	NPL	Secondary	04/05/2022

4. Description of Device:

Cytrans™ Elashield consists of a single composition of P (LA/CL) (L-lactide-ε-caprolactone copolymer), a bioresorbable polymer, and has a white membrane structure with a thickness of about 200 μm. It acts as a barrier to prevent the invasion of soft tissue into the bone defect by covering the affected bone defect, thus promoting bone regeneration in the defect area. It has a two-layer structure, one is a dense layer (solid layer) to prevent the invasion of soft tissues, and the other is a porous layer, which provides flexible operability. It is resorbed into the body via hydrolysis. It is a gamma-ray sterilized material.

5. Indications for Use:

Cytrans™ Elashield is intended for the following uses as a space-making barrier:

- Guided bone regeneration in oral surgery
- Alveolar ridge augmentation
- Guided tissue regeneration in periodontal defects
- Extraction socket site preservation
- Sinus lifts
- Immediate implant placement at time of extraction or delayed placement
- Treatment of associated cystic defect
- The containment of bone grafting materials

6. **Comparison of Technology**

The applicant device and the predicate devices are substantially equivalent in the following points.

- Bioresorbable barrier membrane applied for GBR or GTR
- Indication for use
- Provided in clinically relevant sizes for intra-oral surgical procedures
- Sterility Assurance Level of 10^{-6}.
- Performance evaluation *in vivo*
- Degradation by hydrolysis

The applicant device is different from the predicate devices in the following points.

- The applicant device and the primary predicate device are equivalent in that they are made of polylactic acid-based bioresorbable synthetic polymer, but the detailed composition of the polymers used is different. The reference device differs from the applicant device in that it is made of animal-derived collagen. The applicant device and the reference device are equivalent in that they have a two-layer structure with an intended porous layer and a dense layer, while the primary predicate device has not two-layer structure but just porous.

- The measured tensile strength itself as a physical property of the applicant device and the primary predicate device is equivalent but the breaking distance of the applicant device is greater than that of the both predicate devices. It is concluded that this is due to flexible and rubber-like properties of the applicant device and that there is no problem in clinical use when combined with the performance evaluation *in vivo*.

Based on similarities in intended use, mode of action, chemical composition, and performance testing, Cytrans™ Elashield is substantially equivalent to the predicate devices.

Substantial equivalence to the comparative device

	Applicant device	Primary device	Secondary predicate device	Rationale
Trade name	Cytrans™ Elashield	CytoFlex® Resorb K090083	Geistlich Bio-Gide® K212463	
Manufacturer	GC Corporation	UNICARE BIOMEDICAL, INC.	Geistlich Pharma AG	
Product category	LYC, NPL Bone Grafting Material, Syntheti Class II	LYC Bone Grafting Material, Synthetic Class II	NPL Barrier, Animal Source, Intraoral Class II	Applicant device and primary device are the same. Reference device is different in that the raw material is of animal origin.
Indications for use	Cytrans™ Elashield is intended for the following uses as a space-making barrier: • Guided bone regeneration in oral surgery • Alveolar ridge augmentation • Guided tissue regeneration in periodontal defects • Extraction socket site preservation • Sinus lifts • Immediate implant placement at time of extraction or delayed placement • Treatment of associated cystic defect • The containment of bone grafting materials	CytoFlex® Resorb membranes are intended for use as a space-making barrier in the treatment of periodontal defects and maxillofacial guided tissue regeneration procedures, including preservation and regeneration of alveolar bone height and volume, ridge and extraction site augmentation, sinus lifts, and treatment of associated cystic defects. It is also intended for use as a grafting material containment matrix.	Geistlich Bio-Gide® is intended for the following uses: · 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; and · guided tissue regeneration procedures in periodontal defects. ·	Although verbiage describing is different, indications for use are substantially equivalent between applicant device, primary device and reference device. All devices are applied for GBR or GTR.
Classification of material	Resorbable P(LA/CL) Bilayer membrane	PLA/PGA Membrane	Bilayer collagen membrane	All devices are substantially equivalent in the following respects. · Barrier membrane for bone regeneration · Bioresorbable Applicant device and primary device are the same as made of a bioresorbable synthetic polymer. Applicant device and reference device are the same in terms of having a two-layer structure with an intended porous layer and a dense layer.
Delivery form	Sheet	Sheet	Sheet	No difference between the applicant, the primary, and the reference device.

	Applicant device	Primary device	Secondary predicate device	Rationale
Size	· 15 mm × 25 mm · 25 mm × 25 mm · 30 mm × 40 mm	· 15mmx12mm · 17mmx17mm · 25mmx17mm · 30mmx24mm · 40mmx30mm · 25mmx20mm	Geistlich Bio-Gide® is provided in the following sizes: · 13 x 25 mm · 25 x 25 mm · 30 x 40 mm · 40 x 50 mm · 16 x 22 mm as part of the Combi-Kit Collagen	All devices are substantially equivalent
Thickness	200 µm	300 µm	400 µm	Applicant device is thinner than primary predicate device and reference device. The tensile strength testing showed applicant device has substantially equivalent tensile strength properties to the predicate devices despite the lower.
Chemical composition	P(LA/CL) L-lactide-ε-caprolactone copolymer	Synthetic polyglycolide, polylactide and D,L-lactide/glycolide copolymers	Pig collagen	Applicant device and primary device are the same in terms of synthetic materials which are made of polylactic acid-based bioresorbable synthetic polymer.
Sterility	Gamma irradiation Sterility Assurance Level of 10^{-6}	Ethylene Oxide Sterility Assurance Level of 10^{-6}	Gamma irradiation Sterility Assurance Level of 10^{-6}	All devices are the same in terms of Sterility Assurance Level of 10^{-6}. Applicant device and reference device are the same in that the sterilization method is gamma irradiation.
Storage temperature	4°C - 25°C	15°C - 30°C	15°C - 25°C	Storage temperature differs for the applicant device compared to the primary device and reference device. Test data is included to support that the applicant device meets its identified requirements when stored within the identified temperature range.
Shelf life	2 years	3 years	3 years	Shelf life of applicant is shorter than predicate devices.

7. Performance Bench Tests:

Since there is no international standard, such as ISO, the physical properties of this product were established based on the company specification, ISO 22803.

Performance testing includes:

Property	Test method	Specification
Appearance	Visually check the appearance of the solid and porous layer sur-faces.	**Solid layer (smooth surface):** No fracture or crack shall be found on the surface. (No metallic luster of alu-minum shall be visible when the film for aluminum mount is attached.) **Porous layer (porous surface):** -The surface shall be distinguishable from the solid layer surface without the glossiness of the solid layer. -No foreign matter shall be found.
Compositional analysis	Analyze product composition using an infrared spectropho-tometer	In comparison with the infrared ab-sorption spectrum of the standard product, peaks peculiar to L-lactic acid ε-caprolactone should be recog-nized.
Membrane thickness	Total membrane thickness: Measure the thickness at 5 points of the membrane using a micrometer.	180 - 320 μm
	Solid layer thickness: Using a laser microscope, measure the thickness at 3 points of the solid layer by ob-serving the cut-out cross sec-tion with a 50x objective lens. Measurements are taken in three non-overlapping fields of view.	16 - 80 μm
Solid layer surface texture	The solid layer surface is ob-served under a laser micro-scope (50x objective lens) and measure the biggest pore size. Perform three views with no overlap.	20 μm or less
Tensile strength	Both of specimen (2 x 15 mm) was fixed with jig at 12 mm intervals and its tensile strength at the 30% elongation point was measured at cross head speed of 20 mm/min by using universal testing ma-chine.	0.05 - 0.5 N *Without breaking at 30% elongation point.
Residual solvent	Measure residual amounts of the organic solvent 1,4-diox-ane used in production by us-ing GC-MS.	100 ppm or less

Size	Measured the length and width of a product using micrometer.	S: W 15 ± 1 mm, L 25 ± 1 mm M: W 25 ± 1 mm, L 25 ± 1 mm L: W 30 ± 1 mm, L 40 ± 1 mm

8. **Biocompatibility**

A biocompatibility assessment was completed according to ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

Cytrans™ Elashield is a bioresorbable membrane for GBR or GTR. Medical device categorization by ISO 10993 for biological evaluation of medical devices is as follows.

Category : Implant medical device
Contact : Tissue/bone
Contact duration : Long term (> 30 d)

In conclusion, biocompatibility of Cytrans™ Elashield is an acceptable device from the biological evaluation result.

Cytotoxicity
Based on the criteria of the protocol of ISO 10993-5

Sensitization
Based on the criteria of the protocol of ISO 10993-10

Intracutaneous reactivity
Based on the criteria of the protocol of ISO 10993-23

Material mediated pyrogenicity
Based on the criteria of the protocol of ISO10993-11

Acute systemic toxicity
Based on the criteria of the protocol of ISO 10993-11

Subchronic toxicity
Based on the criteria of the protocol of ISO10993-11

Implantation effects
Based on the criteria of the protocol of ISO10993-6

Genotoxicity
Based on the criteria of the protocol of ISO10993-3

9. Animal Study:

An animal study was conducted to evaluate the substantial equivalence of Cytrans™ Elashield to the predicate device.
The study was performed using a beagle dog mandibular defect model consisting of a two-walled bone defect. Newly formed bone volume was assessed by CT evaluation, and residual material area and biological response were assessed by histological evaluation using H&E and Villanueva Goldner staining at 4, 12, and 26 weeks post-implantation.
No significant difference in newly formed bone volume was observed between Cytrans™ Elashield and the predicate device. Both Cytrans™ Elashield and the predicate device were gradually resorbed in vivo, with the residual

material area decreasing over time. These findings indicate that the materials inhibited soft tissue invasion and maintained space for bone tissue regeneration.
Based on these results, the performance of Cytrans™ Elashield was determined to be substantially equivalent to that of the predicate device.

10. **Conclusion**:
Based on similarities in indications for use, technology, safety and effectiveness, the applicant device is substantially equivalent to the predicate devices.