December 05, 2025

Neo Modulus (Suzhou) Medical Sci-Tech Co., Ltd.
Jade Guo
Manager, Regulatory Affairs
Room 301,302, Building 11, No. 8 Jinfeng Road
Suzhou New District
Suzhou, Jiangsu 215163
CHINA

Re: K250512
Trade/Device Name: Augmented Gingival Matrix
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: November 5, 2025
Received: November 7, 2025

Dear Jade Guo:

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.

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)*
K250512

Device Name
Augmented Gingival Matrix

Indications for Use *(Describe)*
It is indicated for localized gingival augmentation to increase keratinized tissue (KT) around teeth.

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

1. Submitter

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Phone: +86 0512-66062500

Contact Person: Menglei Yu
Date Prepared：Dec 5, 2025

2. Device

Name of Device: Augmented Gingival Matrix (Abbreviated as "AGM")
Common or Usual Name: Gelatin Matrix
Classification Name: Bone Grafting Material (21 CFR 872.3930)
Regulatory Class: II
Product Code: NPL

3. Predicate device

Geistlich Mucograft®, K210280.
No reference devices were used in this submission.

4. Device description

AGM is a three-layer, symmetrical composite matrix intended for oral tissue regeneration. The top and bottom of the product are gelatin layers, which are made of gelatin derived from bovine bone. The gelatin layers are structured as random fiber stacking by in situ cross-linked electrospinning technology and its average diameter is 100 - 900 nm. Users do not need to distinguish between the top and bottom of the product. The middle of the product is polycaprolactone layer (Abbreviated as "PCL layer"), which is thin polycaprolactone film with porous structure.

When adhering to the wound surface, the "inner" gelatin layer, the one facing the wound can increase keratinized tissue (KT) around teeth. The middle of PCL layer promotes the spreading of matrix on wound surface. Along with the "outer" gelatin layer, the PCL layer also acts as physical barrier to prevent foreign objects' invasion.

5. Indications for use

AGM is intended to be used for localized gingival augmentation to increase keratinized tissue (KT) around teeth.

6. Comparison of technological characteristics with the predicate device

A comparison of the subject and predicate device is provided in the table below.

	Subject device	**Predicate device (K210280)**	**Discussion**
Device name	Augmented Gingival Matrix	Geistlich Mucograft®	No discussion required
Regulation	21 CFR 872.3930	21 CFR 872.3930	Same as predicate
Product Code	NPL	NPL	Same as predicate
Device Classification	Barrier, Animal Source, Intraoral	Barrier, Animal Source, Intraoral	Same as predicate
Indications	It is indicated for localized gingival augmentation to increase keratinized tissue (KT) around teeth.	Geistlich Mucograft® and Geistlich Mucograft® Seal are indicated for: • covering of implants placed in immediate or delayed extraction sockets; • localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants; • alveolar ridge reconstruction for prosthetic treatment; and • recession defects for root coverage.	Subset of the indications of the predicate device
Animal Origin Material	Gelatin is derived from bovine bone.	Porcine connective tissue, Porcine skin tissue	Different species and tissue

	Polycaprolactone is not an animal tissue derived material.		
Biocompatibility	Yes	Yes	Same as predicate
Non-Pyrogenic	Yes	Yes	Same as predicate
Resorbable	1.Gelatin is partially absorbed during the product lifetime. 2.Due to its degradation rate, polycaprolactone won't be absorbed during the product lifetime.	Fully absorbed.	Different Device performance and biocompatibility were not affected despite the different materials and the removal of the subject device at 2 weeks.
Sizes	Width: 10mm~30mm, Length: 10mm~40mm	15mm x 20mm 20mm x 30mm 30mm x 40mm	The subject device sizes fall within the range of those of the predicate device
Sterilization	Ethylene Oxide	Gamma Irradiation	Traditional sterilization method
Sterility Assurance Level	10^{-6}	10^{-6}	Same as predicate
Shelf life	2 years	3 years	The shelf life of the product has been validated.

7. Performance data

In vivo and in vitro testing of the subject device was conducted to demonstrate substantial equivalence of the subject device to its predicate device. The following performance data are provided in support of the substantial equivalence determination. Viral inactivation to ensure product safety was performed in accordance with ISO 22442-3.

7.1 Bench

Test Performed	Test Method/Applicable Standards	Results
Appearance	Observe under natural light	Pass
Dimension	Use a digital caliper to test according to the drawing of the corresponding product model models	Pass
Thickness	The thickness gauge is used to measure the sample	Pass
Water Absorption	The sample was placed in purified water at 37°C and the time for complete infiltration was recorded	Pass
Fiber diameter and diameter distribution	Scanning electron microscopy	Pass
Porosity	ISO 15901-1:2016 Evaluation of pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption	Pass
Tearing force	ISO 7198:2016 Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches	Pass
pH	USP<791>	Pass
Heavy Metal	USP<231>	Pass
Sulfated ash	USP<281>	Pass
Total protein	USP<1057>	Pass
EO residuals	ISO 10993-7: 2008 Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	Pass
ECH residuals	ISO 10993-7: 2008 Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals	Pass
Glyoxal residuals	ultraviolet spectrophotometer	Pass
Degree of crosslinking	ultraviolet spectrophotometer	Pass
Sterility	USP<71>	Pass
Bacterial Endotoxins	USP<85>	Pass

7.2 Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the 2023 FDA guidance document “Use of International Standard ISO 10993-1 Biological evaluation of medical devices - Part 1 - Evaluation and testing within a risk management process”, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management

Process," as recognized by FDA. The testing included the following tests:

- Cytotoxicity: ISO 10993-5: 2009: Biological evaluation of medical devices-Part 5-Tests for In Vitro Cytotoxicity
- Sensitization: ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization
- Intracutaneous reactivity: ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests for Irritation
- Systemic toxicity (acute and subacute): ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- Pyrogen Testing: ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- Implantation: ISO 10993-6:2016 Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects after Implantation
- Genotoxicity: ISO 10993-3:2014 Biological Evaluation of Medical Devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

7.3 Animal Study

The performance of the device was compared to that of the predicate device, Geistlich Mucograft® in a canine model, the defect size is 3.0×1.0 cm, the time points are set at 7 days, 14 days, 30 days, and 90 days. The study endpoints include:

Efficacy evaluation endpoints:

- Keratinized gingiva width augmentation measured by periodontal probe
- Epithelial migration distance by quantitative analysis of HE staining
- Newly formed collagen arrangement by qualitative analysis of Masson staining

Safety evaluation endpoints:

- Local effects after implantation according to ISO 10993-6

7.4 Clinical Testing

Prospective, multi-center, open, randomized, controlled, non-inferiority clinical study design of the subject device, AGM, was conducted for comparison with control group of Autologous Free Gingiva, including a total of 5 centers in this trial, and 148 subjects enrolled (74 subjects in the test group and 74 subjects in the control group).

The main efficacy indicator is Augmentation of keratinized gingival width 6 months postoperatively.

Based on the clinical performance as documented in the clinical study, the subject device was found to have a safety and effectiveness profile.

The main efficacy indicator between the two groups has no statistically significant difference (P=0.951), and it can be concluded that the augmentation of keratinized gingival width 6 months postoperatively for the devices in the subject device was noninferior to that of the Autologous Free Gingiva which provides support for the safety and effectiveness of its clinical application.

8. CONCLUSIONS

The non-clinical data support the safety of the device and the verification and validation demonstrate that the AGM device perform as intended. The clinical data demonstrate that the AGM device performs comparably to the predicate device that is currently marketed for the same intended use.