Full Golden Biotech Co., Ltd.
% Mandy Lin
Regulatory Affairs Consultant
Voler Biotech Consulting CO., Ltd
6F.-17, No. 14, Ln. 609, Sec. 5, Chongxin Rd.,
Sanchong Dist.
New Taipei City, 241407
TAIWAN

October 27, 2025

Re: K244006
Trade/Device Name: FG Bone Graft M
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: Class II
Product Code: LYC

Dear Mandy Lin:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on September 17, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter as an administrative correction to include the correct product code

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Andrew Steen, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices, 301-796-6284, Andrew.Steen@fda.hhs.gov.

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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TAIWAN

September 17, 2025

Re: K244006
Trade/Device Name: FG Bone Graft M
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: December 24, 2024
Received: August 22, 2025

Dear Mandy Lin:

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)*
K244006

Device Name
FG Bone Graft M

Indications for Use *(Describe)*
FG Bone Graft M is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects.
These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
Typical uses include:
- Periodontal/Intrabony defects filling
- Ridge augmentation
- Implant preparation, placement in extraction sites
- Sinus lifts
- Cystic cavities filling

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

FG Bone Graft M

510(k) K244006

1. Submission Information

Submitter: Full Golden Biotech Co., Ltd.
3F., No. 27, Sec. 2, Henan Rd., Xitun Dist., Taichung City 407, Taiwan (R.O.C.)
Submitter contact: Chiyu Chen
Tel: +886-912182578
E-mail: cinseagle@gmail.com
Date of preparation: September 17, 2025

2. Device Name and Classification

Product Name:	FG Bone Graft M
Classification Name:	Bone Grafting Material, Synthetic
Common or Usual Name:	Bone grafting material
Regulation Number:	872.3930
Product Code:	LYC

3. Predicate Device(s)

Product Name:	MBCP (K051885)
Common or Usual Name:	Bone grafting material
Regulation Number:	872.3930
Product Code:	LYC

4. Device Description

The Synthetic Bone Substitute, FG Bone Graft M, is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 60% Hydroxyapatite (HA) and 40% beta-Tricalcium Phosphate (β-TCP).

The synthetic bone substitute is presented in a porous form required for the conduction of precursor cells to the defect site to facilitate new bone growth.

This product is provided sterile for single patient use.

The synthetic bone substitute is progressively replaced by new bone according to the remodeling process.

5. Indications for Use

FG Bone Graft M is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects.

These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Typical uses include:

- Periodontal/Intrabony defects filling
- Ridge augmentation
- Implant preparation, placement in extraction sites
- Sinus lifts
- Cystic cavities filling

6. Comparison to the Predicate Device

Items	Predicate Device	Proposed Device
Device Name (Common name)	MBCP	FG Bone Graft M
K. number	K051885	K244006
Regulation Number	21 CFR 872.3930	Substantially equivalent
Product code	LYC	Substantially equivalent
Intended Use	MBCP is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MBCP can be used with autogenous bone grafting materials. Typical uses include:	FG Bone Graft M is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Typical uses include: • Periodontal/Intrabony defects filling

Items	Predicate Device	Proposed Device
	- Periodontal/Infrabony defects -Ridge augmentation - Extraction sites (implant preparation/placement) -Sinus lifts -Cystic cavities	• Ridge Augmentation • Implant preparation, placement in extraction sites • Sinus lifts • Cystic cavities filling
Application	Human: Oral, Periodontal	Substantially equivalent
Performance function	Osteoconductive bone formation	Substantially equivalent
Source	Synthetic	Substantially equivalent
Composition	60% HA	Substantially equivalent
	40% β-TCP	Substantially equivalent
Form	Granules, Small, Medium, and Large	Granules, Small and Medium
Particle size	0.5~1.0 mm 1.0~2.0 mm 2.0~3.0 mm	0.5~1.0 mm 1.0~2.0 mm
Porosity	~70%	Substantially equivalent
Physical morphology	Interconnecting pore structures	Substantially equivalent
Crystallinity (%)	>70 %	Substantially equivalent
Resorption	Partially resorbable	Substantially equivalent
Packaging	Vial in sealed tray with outer carton	Substantially equivalent
Sterility	Sterile (Gamma Irradiation); Non-pyrogenic; One-time single patient use	Substantially equivalent

The FG Bone Graft M has the same indications for use as the predicate device. FG Bone Graft M has similar technological characteristics to the predicate device including overall design, intended use, material composition, and functions. Although the granule size range differs between the subject device and the predicate device, the size range of the subject device remains within that of the predicate. Since the granule size range of the subject device is narrower than that of the predicate, there are no new concerns regarding safety or effectiveness associated with this difference.

7. Performance Data

Non-clinical tests were performed on the proposed device.

The following tests were conducted:

A. Chemical Properties

<table>
<tr><th>Description</th><th>Criteria</th><th>Result</th></tr>
<tr><td>Complete chemical composition, summing to 100% by mass, including all additives and the Chemical Abstracts Service (CAS®) registry number of all components.</td><td>60% Hydroxyapatite (HA) and 40% beta-Tricalcium Phosphate (β-TCP). Equipment inspection error range ± 5%</td><td>60% Hydroxyapatite (HA) and 40% beta-Tricalcium Phosphate (β-TCP). Equipment inspection error range ± 5%</td></tr>
<tr><td>Description of the composition, including an elemental analysis, identifying the trace impurities.</td><td><table><tr><th colspan="2">Conc.(ppm)</th></tr><tr><td>Pb</td><td>≤30</td></tr><tr><td>As</td><td>≤3</td></tr><tr><td>Cd</td><td>≤5</td></tr><tr><td>Hg</td><td>≤5</td></tr></table></td><td><table><tr><th colspan="2">Conc.(ppm)</th></tr><tr><td>Pb</td><td>0</td></tr><tr><td>As</td><td>0.39</td></tr><tr><td>Cd</td><td>0.08</td></tr><tr><td>Hg</td><td>0</td></tr></table></td></tr>
</table>

B. Physical Properties

Description	Criteria	Result
SEM micrographs, showing particle size, shape, and porosity	The product behaves like a porous structure and is similar to the reference product.	The SEM results showed that the surface characteristics of FG Bone Graft M are similar to those of the predicate device (MBCP) via 600X, 1000X, and 3000X SEM photos.

A plot of the resorption of your device versus time showing the time for total clearance or integration under a representative model	Similar trend changes to the comparison products.	~89% degraded by 12 weeks
Healing time, i.e., the earliest time at which implant loading may be successfully attempted	N/A	The defect fill rate was observed to be 21.0% at 4 weeks, increasing to 30.8% by 8 weeks, and reaching up to 41.4% by 12 weeks.
Phase purity, i.e., the relative mass percentages of crystalline and amorphous phases (%)	Similar to the comparison products.	Crystallinity >70 %
Calcium to phosphorous ratio (Ca/P)	Ca/P ratio >1.5	Ca/P ratio: 1.83-1.91
Volumetric porosity (% void space)	The porosity is approximately 70% ± 5% or similar to the predicate device.	Porosity: 67.14%
Particle size distribution plot (μ)	The mean value of the particle size distribution is within the declared specifications, or the median and mode are within the specification range.	0.5- 1.0 mm 1.0- 2.0 mm
pH	Similar trend changes to the predicate device.	~6.6 over 7 days

C. <u>Performance In Vivo-Animal Study</u>

1. Test model:
   - Animal model: Beagle dog, Male, 12-18 months of age.
   - Study design: evaluate bone healing and material degradation at 4, 8, and 12 weeks. Animals were divided into groups: test group (FG Bone Graft M), positive control group (MBCP, a commercial product), and a negative control (empty defect).

2. Defect type:
    - Dental application: The study simulated alveolar bone defects (e.g., post-extraction bone loss) or maxillary sinus augmentation models. Single-walled defects (incomplete truncation, "L" shaped couch, 10 mm in length, 5 mm in width and 5 mm in depth) were designed to prevent spontaneous healing.
    - Creation method: Defects were created surgically using standardized tools (Dental handpiece) to ensure consistent size and shape across groups, following aseptic techniques and animal welfare protocols.
3. Treatment methods
    - Test article: FG Bone Graft M
    - Control article: MBCP
    - Application method: Applied as granules to fill the bone defect.
    - Dosage: Material volume (0.25 cm^3) was determined based on defect size to ensure complete filling, consistent with standard protocols.
4. Endpoints assessed
    - Histological analysis:
    a) New bone formation: Quantification of new bone area or volume within the defect site, assessed via Masson-Goldner staining.
    b) Material degradation: Measurement of residual FG Bone Graft M and MBCP, expressed as a percentage of remaining material, to assess resorption rates.
    c) Inflammatory response: Evaluation of inflammatory cell infiltration (e.g., lymphocytes, macrophages) or adverse tissue reactions to the graft material.
    - Radiographic analysis: Included micro-CT to assess bone density and bone volume.
5. Results
    - New bone formation: New bone formation increased over time at comparable rates to the predicate.
    - Material degradation: FG Bone Graft M degraded at comparable rates to the predicate over 12 weeks.
    - Inflammatory response: Minimal to mild inflammatory response, with no significant adverse reactions.

D. <u>Biocompatibility Testing</u>

The biocompatibility of the device was assessed using the methodology described in ISO 10993-1 and FDA Guidance, “Use of International Standard ISO 10993-1, Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.” The following biocompatibility tests were completed.

Test	Standard
Cytotoxicity	ISO 10993-5
Sensitization	ISO 10993- 10
Irritation	ISO 10993- 10 and ISO 10993- 23
Acute Systemic Toxicity	ISO 10993- 11
Subchronic Systemic Toxicity	ISO 10993- 11 and ISO 10993-6
Pyrogenicity	USP 151 and ISO 10993- 11
Implantation	ISO 10993-6
Genotoxicity	ISO 10993-3

E. Shelf Life

The shelf life was assigned based on accelerated aging studies of both the packaging and the product. The packaging was tested using the burst/creep tests (ASTM F1140), seal peel strength test (ASTM F88), and dye penetration test (ASTM F1929). The product stability, and shelf life of 5 years, was assessed by monitoring chemical composition, Ca/P ratio, impurities, SEM, pH, and water solubility.

F. Sterilization Validation

The validation of gamma irradiation sterilization was performed following ISO 11137-1 and ISO 11137-2, achieving a sterility assurance level of 10^{-6}.

8. Conclusion

Test data indicate that the final properties of FG Bone Graft M are in compliance with the guidance for Bone Grafting Material Devices and are substantially equivalent to the predicate device.