

K243745 FG Bone Graft BAug 29, 2025
267 days to decisionK243745 · Product code: LYC · Dental
Source: <https://www.510kdatabase.net/k243745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Dec 5, 2024
Decision date	Aug 29, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Full Golden Biotech Corporation
Location	Taichung, TW
Contact	Chiyu Chen
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Voler Biotech Consulting CO., Ltd.
Contact	Yvonne Chen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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Device record: <https://www.510kdatabase.net/k243745/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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