FDA 510(k) Premarket Notification

K251818 BONTREE PLUS

CLEARED

Mar 6, 2026
266 days to decision

K251818 · Product code: **LYC** · Dental
Source: https://www.510kdatabase.net/k251818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Jun 13, 2025
Decision date	Mar 6, 2026
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hudens Bio Co., Ltd.**
Location	Gwangju, KR
Contact	Hun Kim
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**K-Bio Solutions**
Contact	Kyungyoon Kang

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