FDA 510(k) Premarket Notification

K253883 Bonalive Maxillofacial

CLEARED

May 14, 2026
161 days to decision

K253883 · Product code: **LYC** · Dental
Source: https://www.510kdatabase.net/k253883/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Dec 4, 2025
Decision date	May 14, 2026
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bonalive , Ltd.**
Location	Turku, FI
Contact	Jenna Saarimäki
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Obelix Consulting**
Contact	Elisa Maldonado-Holmertz

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