

K253883 Bonalive MaxillofacialMay 14, 2026
161 days to decisionK253883 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253883/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 7, 2026