

K233768 Papacarie DuoJul 18, 2024
237 days to decisionK233768 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k233768/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Nov 24, 2023
Decision date	Jul 18, 2024
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elevate Oral Care
Location	West Palm Beach, FL, US
Contact	Steven Pardue
510(k) history	4 submissions · 4 cleared · 2013-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233768/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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