

K250714 FluoroDose VarnishNov 21, 2025
256 days to decisionK250714 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k250714/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Mar 10, 2025
Decision date	Nov 21, 2025
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Centrix, Inc.
Location	Mchenry, IL, US
Contact	Tim White
510(k) history	47 submissions · 47 cleared · 1979-2025

REGULATORY CONSULTANT

Consulting firm	Aztech Regulatory & Quality, LLC
Contact	Joseph Azary

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

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