

K243777 Rennou™ Varnish (3% / Spearmint)May 27, 2025
169 days to decisionK243777 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k243777/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Dec 9, 2024
Decision date	May 27, 2025
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Rennou™ Varnish (3% / Strawberry); Rennou™ Varnish (3% / Cherry); Rennou™ Varnish (3% / Bubble Gum)

APPLICANT

Company	Theodent, LLC
Location	New Orleans, LA, US
Contact	Joseph Fuselier
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Blackwell Device Consulting
Contact	Andrew Fuselier

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/k243777/> 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 May 14, 2026