

K181965 Restore ToothpasteJun 13, 2019
325 days to decisionK181965 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k181965/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Jul 23, 2018
Decision date	Jun 13, 2019
Days to decision	325 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Dr. Collins, Inc.
Location	Irvine, CA, US
Contact	Jiahe Li
510(k) history	2 submissions · 2 cleared · 2019-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181965/> 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 28, 2026