

K171542 TheraBreath Dry Mouth Oral Rinse, TheraBreath Dry Mouth LozengesMar 16, 2018
294 days to decisionK171542 · Product code: LFD · Dental
Source: <https://www.510kdatabase.net/k171542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saliva, Artificial (LFD)
Date received	May 26, 2017
Decision date	Mar 16, 2018
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dr. Harold Katz, LLC (Db a Therabreath
Location	Los Angeles, CA, US
Contact	Harold Katz
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171542/> 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 30, 2026