

K181194 SmartMouth DryMouth Oral RinseFeb 15, 2019
287 days to decisionK181194 · Product code: **LFD** · Dental
Source: <https://www.510kdatabase.net/k181194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saliva, Artificial (LFD)
Date received	May 4, 2018
Decision date	Feb 15, 2019
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Triumph Pharmaceuticals, Inc.
Location	St. Louis, MO, US
Contact	Andrew Burch
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Wood Burditt Group
Contact	H. Carl Jenkins

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181194/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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