FDA 510(k) Premarket Notification

K181194 SmartMouth DryMouth Oral Rinse

CLEARED

Feb 15, 2019
287 days to decision

K181194 · 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