

**K203567 Oral-B Dry Mouth Oral Rinse**Apr 5, 2021  
119 days to decisionK203567 · Product code: LFD · Dental  
Source: <https://www.510kdatabase.net/k203567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saliva, Artificial (LFD)
Date received	Dec 7, 2020
Decision date	Apr 5, 2021
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>The Procter &amp; Gamble Company</b>
Location	Cincinnati, OH, US
Contact	Brenda S. Fuentes
510(k) history	5 submissions · 5 cleared · 2012-2021

**CLINICAL EVIDENCE - NCT04189081****Improvement of Dry Mouth Sufferers After Using an Experimental Dry Mouth Rinse Compared to a Water Control**

Status	Completed
Enrollment	137 patients (actual)
Study sites	1 site
Condition studied	Dry Mouth
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Jul 8, 2020
Sponsor	Procter and Gamble (Industry)

**Primary outcome**

Response to "Relieving the Discomfort of Dry Mouth" From the Modified PPAQ I 4- and 6-hours Post-use on Day 1 of Treatment

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04189081](https://clinicaltrials.gov/study/NCT04189081)

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k203567/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026