

K250390 CloSYS® Dry Mouth Sensitive Mouth RinseMay 19, 2025
97 days to decision

K250390 · Product code: LFD · Dental

Source: <https://www.510kdatabase.net/k250390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saliva, Artificial (LFD)
Date received	Feb 11, 2025
Decision date	May 19, 2025
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rowpar Pharmaceuticals, Inc.
Location	Bridgewater, NJ, US
Contact	Michael Tune
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Innovative Science Solutions (D.B.A Lumanity)
Contact	Steven Weisman

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/k250390/> 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 14, 2026