

K200601 LumiCare Caries Diagnostic RinseMar 29, 2021
385 days to decisionK200601 · Product code: **LFC** · Dental
Source: <https://www.510kdatabase.net/k200601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Caries Detection (LFC)
Date received	Mar 9, 2020
Decision date	Mar 29, 2021
Days to decision	385 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GreenMark Biomedical, Inc.
Location	East Lansing, MI, US
Contact	Steven Bloembergen
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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