FDA 510(k) Premarket Notification

K241568 CrystLCare™ PRO Biorestorative, Fluoride-Plus

CLEARED

Jan 2, 2025
216 days to decision

K241568 · Product code: **LBH** · Dental
Source: https://www.510kdatabase.net/k241568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	May 31, 2024
Decision date	Jan 2, 2025
Days to decision	216 days
Third-party review	No
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	**in2being, LLC**
Contact	Rick Routson

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