

K222323 Black DiamondJun 23, 2023
325 days to decisionK222323 · Product code: **PHR** · Dental
Source: <https://www.510kdatabase.net/k222323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diammine Silver Fluoride Dental Hypersensitivity Varnish (PHR)
Date received	Aug 2, 2022
Decision date	Jun 23, 2023
Days to decision	325 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elevate Oral Care, LLC
Location	West Palm Beach, FL, US
Contact	Steve Pardue
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Elevate Oral Care
Contact	Steve Pardue

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/k222323/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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