FDA 510(k) Premarket Notification

K222459 Centrix FluoroSilver Silver Diamine Fluoride 38%

CLEARED

Oct 27, 2023
438 days to decision

K222459 · Product code: **PHR** · Dental
Source: https://www.510kdatabase.net/k222459/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diammine Silver Fluoride Dental Hypersensitivity Varnish (PHR)
Date received	Aug 15, 2022
Decision date	Oct 27, 2023
Days to decision	438 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Centrix, Inc.**
Location	Mchenry, IL, US
Contact	Greg Moreau
510(k) history	47 submissions · 47 cleared · 1979-2025

REGULATORY CONSULTANT

Consulting firm	**Aztech Regulatory & Quality, LLC**
Contact	Joseph Azary

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