

K230262 BruxZir™ Incisal Coloring LiquidMay 16, 2023
105 days to decisionK230262 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k230262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jan 31, 2023
Decision date	May 16, 2023
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prismatik Dentalcraft, Inc.
Location	Newport Beach, CA, US
Contact	So Hyun Park
510(k) history	57 submissions · 57 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230262/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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