

K254283 BruxZir® Shaded 16 PLUSJan 30, 2026
30 days to decisionK254283 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k254283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powder, Porcelain (EIH)
Date received	Dec 31, 2025
Decision date	Jan 30, 2026
Days to decision	30 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	Park So Hyun
510(k) history	57 submissions · 57 cleared · 2010-2026

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