

K220816 BruxZir NOWAug 2, 2022
134 days to decisionK220816 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k220816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Mar 21, 2022
Decision date	Aug 2, 2022
Days to decision	134 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/k220816/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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