

**K213425 BruxZir Esthetic**Nov 17, 2021  
27 days to decisionK213425 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k213425/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powder, Porcelain (EIH)
Date received	Oct 21, 2021
Decision date	Nov 17, 2021
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213425/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026