

**K200131 BruxZir Steel**Jun 10, 2020  
141 days to decisionK200131 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k200131/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jan 21, 2020
Decision date	Jun 10, 2020
Days to decision	141 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/k200131/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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