

K252446 BruxZir® NOWSep 3, 2025
30 days to decisionK252446 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k252446/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Powder, Porcelain (EIH) |
| Date received | Aug 4, 2025 |
| Decision date | Sep 3, 2025 |
| 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 | So Hyun Park |
| 510(k) history | 57 submissions · 57 cleared · 2010-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252446/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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