

**K231859 PrimmaArt**Nov 26, 2024  
522 days to decisionK231859 · Product code: **EBG** · Dental  
Source: <https://www.510kdatabase.net/k231859/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Jun 23, 2023
Decision date	Nov 26, 2024
Days to decision	522 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentscare Ltda</b>
Location	Joinville, BR
Contact	Roberta Uyara
510(k) history	10 submissions · 10 cleared · 2019-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>United Regulatory, LLC</b>
Contact	Rodrigo Abreu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231859/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026