

**K201707 Opallis, Opallis Flow**Dec 22, 2020  
183 days to decisionK201707 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k201707/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jun 22, 2020
Decision date	Dec 22, 2020
Days to decision	183 days
Third-party review	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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201707/> 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 25, 2026