

**K102984 AURA**Dec 8, 2010  
62 days to decisionK102984 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k102984/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Oct 7, 2010
Decision date	Dec 8, 2010
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sdi Limited</b>
Location	Bayswater, AU
Contact	RUTH EZEKIEL
510(k) history	6 submissions · 6 cleared · 2010-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102984/> 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 26, 2026