

**K250778 Sil-Flow**May 23, 2025  
70 days to decisionK250778 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k250778/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 14, 2025
Decision date	May 23, 2025
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dsi Dental Solutions, Ltd.</b>
Location	Ashdod, IL
Contact	Shlomi Krasner
Website	<a href="https://www.dsisrael.com/">https://www.dsisrael.com/</a>
510(k) history	2 submissions · 2 cleared · 2020-2025

Dsi Dental Solutions, Ltd. is a leading dental supplier based in Israel with a manufacturing facility in Ashdod, IL. The company manufactures over 1,200 dental products and solutions for dental professionals worldwide. The company has received FDA 510(k) clearances from total submissions. Dental devices represent 100% of its regulatory submissions. Dsi Dental Solutions achieved its first FDA clearance in 2020 and most recently in 2025, demonstrating continued regulatory activity and product innovation. The company's cleared device portfolio includes dental implant systems...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Blackwell Device Consulting</b>
Contact	Angela Blackwell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k250778/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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