

**K231263 Fusion Core DC Flo**Jan 5, 2024  
248 days to decisionK231263 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k231263/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 2, 2023
Decision date	Jan 5, 2024
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fusion Flo; Fusion Flo SE; Fusion 1 Seal; Magna NT

**APPLICANT**

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Company	<b>Prevest Denpro Limited</b>
Location	Bari Brahmana, IN
Contact	Atul Modi
510(k) history	7 submissions · 7 cleared · 2021-2024

**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)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231263/> 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 13, 2026