

**K261071 DIAFIL Bulk FLOW (Economic Package)**May 19, 2026  
48 days to decisionK261071 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k261071/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 1, 2026
Decision date	May 19, 2026
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	DIAFIL Bulk FLOW (Refill Package);DIAFIL Bulk FLOW (0.5g)

**APPLICANT**

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Company	<b>DiaDent Group International</b>
Location	Chungcheong Buk-Do, KR
Contact	Seung-Geun Lee
510(k) history	20 submissions · 20 cleared · 2013-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261071/> 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 June 5, 2026