

**K192510 DIAFIL & DIAFIL Capsule**Mar 20, 2020  
190 days to decisionK192510 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k192510/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 12, 2019
Decision date	Mar 20, 2020
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DiaDent Group International</b>
Location	Chungcheong Buk-Do, KR
Contact	Kab Sun Lee
510(k) history	19 submissions · 19 cleared · 2013-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192510/> 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 27, 2026