

**K190597 BRILLIANT EverGlow Flow**Jun 21, 2019  
106 days to decisionK190597 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k190597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 7, 2019
Decision date	Jun 21, 2019
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coltene/Whaledent AG</b>
Location	New York, NY, US
Contact	Wolfgang Dorner
510(k) history	16 submissions · 16 cleared · 2005-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190597/> 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 June 23, 2026