

**K230644 Signum opaque F**Sep 7, 2023  
183 days to decisionK230644 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k230644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 8, 2023
Decision date	Sep 7, 2023
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kulzer, LLC</b>
Location	South Bend, IN, US
Contact	David Vincent
510(k) history	7 submissions · 7 cleared · 2022-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230644/> 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 26, 2026