

**K062515 RETENTION FLOW OPAQUE**Nov 22, 2006  
86 days to decisionK062515 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k062515/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 28, 2006
Decision date	Nov 22, 2006
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Heraeus Kulzer,GmbH</b>
Location	South Bend, IN, US
Contact	CHERYL V ZIMMERMAN
510(k) history	10 submissions · 10 cleared · 2004-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062515/> 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 20, 2026