

**K160049 Charisma**Nov 15, 2016  
309 days to decisionK160049 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k160049/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jan 11, 2016
Decision date	Nov 15, 2016
Days to decision	309 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Heraeus Kulzer, LLC, Mitsui Chemicals Group</b>
Location	South Bend, IN, US
Contact	Jamie Cleveland
510(k) history	2 submissions · 2 cleared · 2015-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160049/> 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 2, 2026