

**K152113 BioHPP - breCAM.BioHPP**Jul 21, 2016  
358 days to decisionK152113 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k152113/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jul 29, 2015
Decision date	Jul 21, 2016
Days to decision	358 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bredent GmbH &amp; Co. KG</b>
Location	Tuttlingen, Baden Wurttemberg, DE
Contact	Stefanie Bochtler
510(k) history	3 submissions · 3 cleared · 2010-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152113/> 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 25, 2026