

**K222723 AMBARINO High-Class**Sep 9, 2022  
1 days to decisionK222723 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k222723/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 8, 2022
Decision date	Sep 9, 2022
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Creamed GmbH &amp; Co. Produktions- Und Handels KG</b>
Location	Marburg, DE
Contact	Robert Lemmer
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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