

**K123761 VITA ENAMIC STAINS**Mar 1, 2013  
84 days to decisionK123761 · Product code: **EBD** · Dental  
Source: <https://www.510kdatabase.net/k123761/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coating, Filling Material, Resin (EBD)
Date received	Dec 7, 2012
Decision date	Mar 1, 2013
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovation Meditech GmbH</b>
Location	Brea, CA, US
Contact	ELIZABETH WOLFSEN
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123761/> 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 9, 2026