

**K083438 BIFIX SE**Feb 13, 2009  
85 days to decisionK083438 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k083438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Nov 20, 2008
Decision date	Feb 13, 2009
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Voco GmbH</b>
Location	Denver, CO, US
Contact	TH. PLAUMANN
Website	<a href="https://www.voco.dental">https://www.voco.dental</a>
510(k) history	119 submissions · 119 cleared · 1991-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083438/> 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 23, 2026