

**K160800 DuoCem**Nov 16, 2016  
238 days to decisionK160800 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k160800/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Mar 23, 2016
Decision date	Nov 16, 2016
Days to decision	238 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Coltene/Whaledent AG</b>
Location	New York, NY, US
Contact	Silke Wallaschek
510(k) history	16 submissions · 16 cleared · 2005-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160800/> 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