

**K053438 GLASS CERAMICS**Jan 18, 2006  
40 days to decisionK053438 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k053438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Dec 9, 2005
Decision date	Jan 18, 2006
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3M Espe AG Dental Products</b>
Location	Bavaria D-82228 Seefeld, DE
Contact	SABINE KRISCHER
510(k) history	24 submissions · 24 cleared · 2002-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053438/> 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 July 1, 2026