

**K170050 Z-CAD smile**Aug 23, 2018  
595 days to decisionK170050 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k170050/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jan 5, 2017
Decision date	Aug 23, 2018
Days to decision	595 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Metoxit AG</b>
Location	Austin, TX, US
Contact	Dipl.-Ing Stefan Leyen
510(k) history	2 submissions · 2 cleared · 2007-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170050/> 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 May 29, 2026