

**K170834 CERABIEN ZR**Oct 17, 2017  
211 days to decisionK170834 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k170834/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Mar 20, 2017
Decision date	Oct 17, 2017
Days to decision	211 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Kuraray Noritake Dental, Inc.</b>
Location	New York, NY, US
Contact	Yasujiro Ohara
510(k) history	32 submissions · 32 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170834/> 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 31, 2026