

**K080146 ZIRKONDENT**Jun 6, 2008  
136 days to decisionK080146 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k080146/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jan 22, 2008
Decision date	Jun 6, 2008
Days to decision	136 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ergometa</b>
Location	Aliso Viejo, CA, US
Contact	MIKE ARTEMOV
510(k) history	1 submissions · 1 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080146/> 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 25, 2026