

**K123615 IRIS - HIGH STRENGTH GLASS CERAMIC**Feb 22, 2013  
91 days to decisionK123615 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k123615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Nov 23, 2012
Decision date	Feb 22, 2013
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentsply Intl.</b>
Location	Walker, MI, US
Contact	HELEN LEWIS
510(k) history	279 submissions · 279 cleared · 1976-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123615/> 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 19, 2026