

**K043312 NOBELRONDO DENTAL CERAMIC - ZIRCONIA**Feb 1, 2005  
62 days to decisionK043312 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k043312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Dec 1, 2004
Decision date	Feb 1, 2005
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nobel Biocare USA, LLC</b>
Location	Yorba Linda,, CA, US
Contact	ELIZABETH J MASON
510(k) history	9 submissions · 9 cleared · 2005-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043312/> 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 6, 2026