

**K212259 Zirdent Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank**Nov 12, 2021  
115 days to decisionK212259 · Product code: **EIH** · Dental  
Source: <https://www.510kdatabase.net/k212259/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jul 20, 2021
Decision date	Nov 12, 2021
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zirdent New Material Co., Ltd.</b>
Location	Changsha, CN
Contact	Jia Li
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Guangzhou Junyi Information Technology Co., Ltd.</b>
Contact	Jinghua Zhou

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212259/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026