

**K240586 Additive Manufacturing Zirconia Customized Restoration**Oct 3, 2024  
216 days to decisionK240586 · Product code: ELL · Dental  
Source: <https://www.510kdatabase.net/k240586/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Teeth, Porcelain (ELL)
Date received	Mar 1, 2024
Decision date	Oct 3, 2024
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou Thales Medtech Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Wang Shuo
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Beijing Xinranyicheng Medicine &amp; Technology Co., Ltd.</b>
Contact	Chen Kaimin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240586/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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