

**K233125 Zirconia Block**Jan 12, 2024  
107 days to decisionK233125 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k233125/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Sep 27, 2023
Decision date	Jan 12, 2024
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou Ivista Medical Devices Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Yao Cheng
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233125/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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