

**K223253 Non-Sterile Zirconia Block (ARENA Star, Mont Blanc)**Feb 27, 2023  
129 days to decisionK223253 · Product code: **EIH** · Dental  
Source: <https://www.510kdatabase.net/k223253/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Oct 21, 2022
Decision date	Feb 27, 2023
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arum Dentistry Co., Ltd.</b>
Location	Yuseong-Gu, Daejeon, KR
Contact	Hyang Mi Lee
510(k) history	17 submissions · 17 cleared · 2020-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Withus Group, Inc.</b>
Contact	April Lee

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/k223253/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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