

K250063 ARENA Star, Galaxy StarJul 10, 2025
181 days to decisionK250063 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k250063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jan 10, 2025
Decision date	Jul 10, 2025
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arum Dentistry Co., Ltd.
Location	Yuseong-Gu, Daejeon, KR
Contact	Choi Won-Yi
510(k) history	17 submissions · 17 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250063/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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