

K252165 ZIRCONOMER POct 28, 2025
110 days to decisionK252165 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k252165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Jul 10, 2025
Decision date	Oct 28, 2025
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shofu Dental Corporation
Location	San Marcos, CA, US
Contact	Malzyner Mauro
510(k) history	38 submissions · 38 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252165/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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