

K254063 iCEM Universal PlusDec 19, 2025
2 days to decisionK254063 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k254063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Cement, Dental (EMA)
Date received	Dec 17, 2025
Decision date	Dec 19, 2025
Days to decision	2 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kulzer, LLC
Location	South Bend, IN, US
Contact	Lucas Harmon
510(k) history	7 submissions · 7 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254063/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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