

K253337 REGEN Bioactive CementApr 15, 2026
197 days to decisionK253337 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k253337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Sep 30, 2025
Decision date	Apr 15, 2026
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inter-Med, Inc.
Location	Racine, WI, US
Contact	Alex Johnson
510(k) history	8 submissions · 8 cleared · 2009-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253337/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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