

K250566 EsCem RMGIJun 20, 2025
114 days to decisionK250566 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k250566/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Feb 26, 2025
Decision date	Jun 20, 2025
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spident Co., Ltd.
Location	Incheon, KR
Contact	Hyemin Kwon
510(k) history	17 submissions · 17 cleared · 2009-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250566/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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