

K252785 TopCEM Vigor SA Self-Adhesive Resin CementDec 12, 2025
101 days to decisionK252785 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k252785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Sep 2, 2025
Decision date	Dec 12, 2025
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rizhao Huge Biomaterials Company, Ltd.
Location	Rizhao City, CN
Contact	Maggie Zheng
510(k) history	13 submissions · 13 cleared · 2020-2025

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