

K242572 TopCEM-Try in Veneer Try-in GelDec 20, 2024
113 days to decisionK242572 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k242572/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 29, 2024
Decision date	Dec 20, 2024
Days to decision	113 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242572/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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