

K251271 TempFIT Temporary Crown and Bridge ResinJun 23, 2025
60 days to decisionK251271 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k251271/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Apr 24, 2025
Decision date	Jun 23, 2025
Days to decision	60 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/k251271/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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