

K250946 Denture Base Resin DT20Mar 31, 2025
3 days to decisionK250946 · Product code: **EBI** · Dental
Source: <https://www.510kdatabase.net/k250946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Mar 28, 2025
Decision date	Mar 31, 2025
Days to decision	3 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou SHINING3D Dental Technology Co., Ltd.
Location	Hangzhou, CN
Contact	Yuzhuo Wang
510(k) history	5 submissions · 5 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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