

K253053 Dura-Crown (CB21-A1/CB21-A2/CB21-A3/CB21-B1)Sep 23, 2025
1 days to decisionK253053 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k253053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 22, 2025
Decision date	Sep 23, 2025
Days to decision	1 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	Jiachen Yang
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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