

K251578 BEAUTIFIL IIMay 27, 2025
5 days to decisionK251578 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k251578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 22, 2025
Decision date	May 27, 2025
Days to decision	5 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shofu Dental Corporation
Location	San Marcos, CA, US
Contact	Malzyner Mauro
510(k) history	38 submissions · 38 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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