

K261246 SRGC-06Jun 18, 2026
63 days to decisionK261246 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k261246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 16, 2026
Decision date	Jun 18, 2026
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GC America, Inc.
Location	Alsip, IL, US
Contact	Futoshi Fusejima
510(k) history	127 submissions · 127 cleared · 1993-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k261246/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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