

K251946 G aenial Universal Injectable IIAug 29, 2025
65 days to decisionK251946 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k251946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jun 25, 2025
Decision date	Aug 29, 2025
Days to decision	65 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	125 submissions · 125 cleared · 1993-2025

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