

K070190 GRADIA DIRECT XMar 12, 2007
49 days to decisionK070190 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k070190/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jan 22, 2007
Decision date	Mar 12, 2007
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	GC America, Inc.
Location	Alsip, IL, US
Contact	TERRY L JORITZ-LYONS
510(k) history	126 submissions · 126 cleared · 1993-2026

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