

K173500 NMF004AMar 8, 2018
115 days to decisionK173500 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k173500/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Nov 13, 2017
Decision date	Mar 8, 2018
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GC America, Inc.
Location	Alsip, IL, US
Contact	Mark Heiss
510(k) history	125 submissions · 125 cleared · 1993-2025

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