

K211259 Renamel BulkfillJun 24, 2021
59 days to decisionK211259 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k211259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 26, 2021
Decision date	Jun 24, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Cosmedent, Inc.
Location	Chicago, IL, US
Contact	Gary Chuven
510(k) history	28 submissions · 28 cleared · 1986-2024

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