

K222435 Renamel® MicrohybridOct 11, 2022
60 days to decisionK222435 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k222435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 12, 2022
Decision date	Oct 11, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Renamel® Flowable Microhybrid

APPLICANT

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

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