

K242097 DenMat Bulk Fill CompositeOct 15, 2024
89 days to decisionK242097 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k242097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jul 18, 2024
Decision date	Oct 15, 2024
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Den-Mat Holdings, LLC
Location	Santa Maria, CA, US
Contact	Kim Maynes
510(k) history	8 submissions · 8 cleared · 2008-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242097/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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