

K220605 Venus Bulk Flow ONEApr 21, 2022
50 days to decisionK220605 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k220605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 2, 2022
Decision date	Apr 21, 2022
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kulzer, LLC
Location	South Bend, IN, US
Contact	Marc Henn
510(k) history	7 submissions · 7 cleared · 2022-2026

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