

K232994 Vittra APS Unique FlowOct 18, 2024
392 days to decisionK232994 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k232994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 22, 2023
Decision date	Oct 18, 2024
Days to decision	392 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentscare Ltda
Location	Joinville, BR
Contact	Paula Cristine de Oliveira
510(k) history	10 submissions · 10 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	United Regulatory, LLC
Contact	Rodrigo Abreu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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