

K260783 Venus Diamond

Mar 11, 2026
1 days to decision

K260783 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k260783/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 10, 2026
Decision date	Mar 11, 2026
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Venus Diamond Flow; Venus Pearl; Venus Bulk Flow One

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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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Device record: <https://www.510kdatabase.net/k260783/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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