

K183380 Tetric PowerFillMar 14, 2019
98 days to decisionK183380 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k183380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Dec 6, 2018
Decision date	Mar 14, 2019
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ivoclar Vivadent, AG
Location	Amherst, NY, US
Contact	Schaan Cakebread
510(k) history	31 submissions · 31 cleared · 2004-2022

REGULATORY CONSULTANT

Consulting firm	Ivoclar Vivadent, Inc.
Contact	Lori Aleshin

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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