

K193537 Omnichroma FlowAug 19, 2020
243 days to decisionK193537 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k193537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Dec 20, 2019
Decision date	Aug 19, 2020
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tokuyama Dental Corporation
Location	Washington, DC, US
Contact	Keith A. Barritt
510(k) history	19 submissions · 19 cleared · 2003-2021

REGULATORY CONSULTANT

Consulting firm	Fish & Richardson, P.C.
Contact	Keith A. Barritt

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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