FDA 510(k) Premarket Notification

K231263 Fusion Core DC Flo

CLEARED

Jan 5, 2024
248 days to decision

K231263 · Product code: **EBF** · Dental
Source: https://www.510kdatabase.net/k231263/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 2, 2023
Decision date	Jan 5, 2024
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fusion Flo; Fusion Flo SE; Fusion 1 Seal; Magna NT

APPLICANT

Company	**Prevest Denpro Limited**
Location	Bari Brahmana, IN
Contact	Atul Modi
510(k) history	7 submissions · 7 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Blackwell Device Consulting**
Contact	Angela Blackwell

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