

K251283 Once-Fil FlowJun 6, 2025
42 days to decisionK251283 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k251283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 25, 2025
Decision date	Jun 6, 2025
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mediclus Co., Ltd.
Location	Cheongju-Si, KR
Contact	Ku Da Hyeon
510(k) history	12 submissions · 12 cleared · 2023-2026

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