

K241147 Any-ComSep 26, 2024
154 days to decisionK241147 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k241147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 25, 2024
Decision date	Sep 26, 2024
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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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