

K250823 Any-Com FlowApr 14, 2025
27 days to decisionK250823 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k250823/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 18, 2025
Decision date	Apr 14, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No

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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250823/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026