

**K252465 Any-Core**Dec 5, 2025  
121 days to decisionK252465 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k252465/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 6, 2025
Decision date	Dec 5, 2025
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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