

**K250763 Reon**May 12, 2025  
60 days to decisionK250763 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k250763/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 13, 2025
Decision date	May 12, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C.E.I.B.Med</b>
Location	Seoul-Si, KR
Contact	Hyo jeong Kim
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>GMSC Co., Ltd.</b>
Contact	Jong-Hyun Kim

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250763/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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