

K260819 Any-Com SealMay 1, 2026
49 days to decisionK260819 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k260819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Mar 13, 2026
Decision date	May 1, 2026
Days to decision	49 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260819/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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