

K261728 One-Fil LC

Jul 21, 2026
56 days to decision

K261728 · Product code: **EJK** · Dental
Source: <https://www.510kdatabase.net/k261728/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Liner, Cavity, Calcium Hydroxide (EJK)
Date received	May 26, 2026
Decision date	Jul 21, 2026
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mediclus Co., Ltd.
Location	Cheongju-Si, KR
Contact	Ku Da Hyeon
510(k) history	14 submissions · 14 cleared · 2023-2026