

K253167 Any-PasteJan 12, 2026
108 days to decisionK253167 · Product code: **KIF** · Dental
Source: <https://www.510kdatabase.net/k253167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Sep 26, 2025
Decision date	Jan 12, 2026
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253167/> 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 14, 2026