

K232182 One-FilJan 26, 2024
186 days to decisionK232182 · Product code: **KIF** · Dental
Source: <https://www.510kdatabase.net/k232182/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Jul 24, 2023
Decision date	Jan 26, 2024
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232182/> 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 13, 2026