

**K243353 One-Fil Putty**Mar 14, 2025  
136 days to decisionK243353 · Product code: **KIF** · Dental  
Source: <https://www.510kdatabase.net/k243353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Oct 29, 2024
Decision date	Mar 14, 2025
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>LK Consulting Group USA, Inc.</b>
Contact	Priscilla Chung

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/k243353/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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