

**K251884 One-Fil Putty Injectable**Aug 22, 2025  
63 days to decisionK251884 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k251884/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Resin, Root Canal Filling (KIF)
Date received	Jun 20, 2025
Decision date	Aug 22, 2025
Days to decision	63 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	Ku Da-Hyeon
510(k) history	12 submissions · 12 cleared · 2023-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251884/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026