

K253797 One-StopFeb 27, 2026
91 days to decisionK253797 · Product code: **MVL** · Dental
Source: <https://www.510kdatabase.net/k253797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cord, Retraction (MVL)
Date received	Nov 28, 2025
Decision date	Feb 27, 2026
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253797/> 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