

K243910 RetraxilSep 24, 2025
279 days to decisionK243910 · Product code: **MVL** · Dental
Source: <https://www.510kdatabase.net/k243910/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cord, Retraction (MVL)
Date received	Dec 19, 2024
Decision date	Sep 24, 2025
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kulzer, LLC
Location	South Bend, IN, US
Contact	Lucas Harmon
510(k) history	7 submissions · 7 cleared · 2022-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243910/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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