FDA 510(k) Premarket Notification

K243910 Retraxil

CLEARED

Sep 24, 2025
279 days to decision

K243910 · 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