FDA 510(k) Premarket Notification

K253392 Synergy Disc Instruments

CLEARED

Mar 27, 2026
178 days to decision

K253392 · Product code: **QLQ** · Orthopedic
Source: https://www.510kdatabase.net/k253392/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Instruments Designed For Use With Total Disc Replacement Devices (QLQ)
Date received	Sep 30, 2025
Decision date	Mar 27, 2026
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Synergy Spine Solutions, Inc.**
Location	Louisville, CO, US
Contact	Josh Butters
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Veronica Downen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov