

K250554 prodisc® L InstrumentsApr 25, 2025
59 days to decisionK250554 · Product code: **QLQ** · Orthopedic
Source: <https://www.510kdatabase.net/k250554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Instruments Designed For Use With Total Disc Replacement Devices (QLQ)
Date received	Feb 25, 2025
Decision date	Apr 25, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Centinel Spine, LLC
Location	West Chester, PA, US
Contact	Jessica Staub
Website	https://centinelspine.com
510(k) history	3 submissions · 3 cleared · 2022-2025

Centinel Spine, LLC is a specialized spine medical device company focused on total disc replacement technology. The company develops motion-preservation and disc arthroplasty solutions for cervical and lumbar spinal disease, with a manufacturing facility in West Chester, US. Centinel Spine has received FDA 510(k) clearances from total submissions since its first clearance in 2022. The company specializes exclusively in Orthopedic devices, representing 100% of its regulatory submissions. The latest clearance was issued in 2025, confirming active regulatory engagement. The ...