FDA 510(k) Premarket Notification

CLEARED

K242869 prodisc® L Instruments

Dec 17, 2024
88 days to decision

K242869 · Product code: **QLQ** · Orthopedic
Source: https://www.510kdatabase.net/k242869/

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 20, 2024
Decision date	Dec 17, 2024
Days to decision	88 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 ...