FDA 510(k) Premarket Notification

CLEARED

K221848 prodisc C SK, prodisc C Nova, and prodisc C Vivo Instruments

Aug 19, 2022
56 days to decision

K221848 · Product code: **QLQ** · Orthopedic
Source: https://www.510kdatabase.net/k221848/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Instruments Designed For Use With Total Disc Replacement Devices (QLQ)
Date received	Jun 24, 2022
Decision date	Aug 19, 2022
Days to decision	56 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 ...

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Justin Eggleton

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