

K232167 VySpan™ PCT SystemSep 27, 2023
68 days to decisionK232167 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k232167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Posterior Cervical Screw System (NKG)
Date received	Jul 21, 2023
Decision date	Sep 27, 2023
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vy Spine, LLC
Location	Tallahassee, FL, US
Contact	Jordan Hendrickson
Website	https://vyspine.com
510(k) history	21 submissions · 21 cleared · 2021-2026

Vy Spine, LLC develops and manufactures orthopedic spinal implants and surgical solutions. The company offers a comprehensive product portfolio spanning cervical, thoracic, lumbar, and sacroiliac spine applications. With a manufacturing facility in Tallahassee, US, Vy Spine combines core spine technologies with innovative materials and designs to address simple to complex surgical needs. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2021. All submissions have focused on orthopedic devices. The latest clearance in 2026 r...