

K231744 VyLink™ Spinal Screw SystemOct 13, 2023
121 days to decisionK231744 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k231744/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 14, 2023
Decision date	Oct 13, 2023
Days to decision	121 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...