

K253432 DiversiVy™ Facet Screw SystemMar 19, 2026
169 days to decisionK253432 · Product code: **MRW** · Orthopedic
Source: <https://www.510kdatabase.net/k253432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Oct 1, 2025
Decision date	Mar 19, 2026
Days to decision	169 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...