

**K223513 UniVy™ OsteoVy™-Ti Cervical IBF System**Apr 18, 2023  
147 days to decisionK223513 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k223513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 22, 2022
Decision date	Apr 18, 2023
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vy Spine, LLC</b>
Location	Tallahassee, FL, US
Contact	Jordan Hendrickson
Website	<a href="https://vyspine.com">https://vyspine.com</a>
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...