FDA 510(k) Premarket Notification

CLEARED

K223412 LumiVy™ Lumbar IBF System

Jan 6, 2023
58 days to decision

K223412 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k223412/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 9, 2022
Decision date	Jan 6, 2023
Days to decision	58 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...