FDA 510(k) Premarket Notification

K212930 LumiVy Lumbar IBF System

CLEARED

Feb 16, 2022
155 days to decision

K212930 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k212930/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 14, 2021
Decision date	Feb 16, 2022
Days to decision	155 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...