

K251302 OptiMesh Multiplanar Expandable Interbody Fusion System

Dec 15, 2025
231 days to decision

K251302 · Product code: **OQB** · Orthopedic
Source: <https://www.510kdatabase.net/k251302/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Body Graft Containment Device (OQB)
Date received	Apr 28, 2025
Decision date	Dec 15, 2025
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spineology, Inc.
Location	Stillwater, MN, US
Contact	Megan Polos
510(k) history	54 submissions · 51 cleared · 1999-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251302/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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