FDA 510(k) Premarket Notification

K254017 SWINGO-3D Lumbar Cage System

CLEARED

Feb 26, 2026
73 days to decision

K254017 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k254017/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 15, 2025
Decision date	Feb 26, 2026
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Implanet**
Location	Allee Francois Magendie, FR
Contact	Regis Le Couedic
510(k) history	3 submissions · 3 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Jen McBride

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov