

K253011 Catalyft PL Expandable Interbody System

Jul 17, 2026
301 days to decision

K253011 · Product code: MAX · Orthopedic
Source: <https://www.510kdatabase.net/k253011/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 19, 2025
Decision date	Jul 17, 2026
Days to decision	301 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	Michelle Obenauer
510(k) history	173 submissions · 162 cleared · 2000-2026