FDA 510(k) Premarket Notification

K251444 Endoskeleton™ Interbody Systems

CLEARED

Sep 4, 2025
118 days to decision

K251444 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k251444/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 9, 2025
Decision date	Sep 4, 2025
Days to decision	118 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	Pamela Hopkins
510(k) history	170 submissions · 159 cleared · 2000-2026