

K252113 PRADO™ Lumbar Interbody Fusion SystemAug 5, 2025
29 days to decisionK252113 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k252113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 7, 2025
Decision date	Aug 5, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bethesda Medical Devices
Location	Brunswick, OH, US
Contact	Amanda Shade
510(k) history	1 submissions · 1 cleared · 2025-2025

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