

**K251444 Endoskeleton™ Interbody Systems**Sep 4, 2025  
118 days to decisionK251444 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k251444/>**SUBMISSION DETAILS**

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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**

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Company	<b>Medtronic Sofamor Danek USA, Inc.</b>
Location	Memphis, TN, US
Contact	Pamela Hopkins
510(k) history	170 submissions · 159 cleared · 2000-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251444/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026