

**K212653 Catalyft LS Expandable Interbody System**Nov 19, 2021  
88 days to decisionK212653 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k212653/>**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	Aug 23, 2021
Decision date	Nov 19, 2021
Days to decision	88 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	Madhuvanathi Soundirarajan
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/k212653/> 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