

**K191788 CAPSTONE Spinal System, CLYDESDALE PTC Spinal System, CRESCENT Spinal System, CRESCENT Spinal System Titanium, DIVERGENCE-L Anterior/Oblique Lumbar Fusion System**Mar 23, 2020  
264 days to decisionK191788 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k191788/>**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	Jul 3, 2019
Decision date	Mar 23, 2020
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek USA, Inc.</b>
Location	Memphis, TN, US
Contact	Mia Wiggins
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/k191788/> 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 15, 2026