

**K094025 CRESCENT SPINAL SYSTEM**Apr 26, 2010  
117 days to decisionK094025 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k094025/>**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	Dec 30, 2009
Decision date	Apr 26, 2010
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek</b>
Location	Memphis, TN, US
Contact	JENNIFER HACKNEY
510(k) history	154 submissions · 147 cleared · 2002-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k094025/> 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 16, 2026