

**K094042 PEEK PREVAIL CERVICAL INTERBODY DEVICE**Jun 30, 2010  
182 days to decisionK094042 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k094042/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Dec 30, 2009
Decision date	Jun 30, 2010
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek</b>
Location	Memphis, TN, US
Contact	JUSTINE VIERA
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/k094042/> 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 17, 2026