

**K003780 VERTEX RECONSTRUCTION SYSTEM**Sep 28, 2001  
295 days to decisionK003780 · Product code: **KWP** · Orthopedic  
Source: <https://www.510kdatabase.net/k003780/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Dec 7, 2000
Decision date	Sep 28, 2001
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek, Inc.</b>
Location	Memphis, TN, US
Contact	RICHARD W TREHARNE
510(k) history	99 submissions · 89 cleared · 2000-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003780/> 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