

**K081297 VERTEX RECONSTRUCTION SYSTEM**Jun 11, 2008  
35 days to decisionK081297 · Product code: **KWP** · Orthopedic  
Source: <https://www.510kdatabase.net/k081297/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	May 7, 2008
Decision date	Jun 11, 2008
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek</b>
Location	Memphis, TN, US
Contact	CHRISTINE SCIFERT
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/k081297/> 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