

**K964159 CD SPINAL SYSTEM**Oct 16, 1997  
365 days to decisionK964159 · Product code: **KWP** · Orthopedic  
Source: <https://www.510kdatabase.net/k964159/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Oct 16, 1996
Decision date	Oct 16, 1997
Days to decision	365 days
Third-party review	No

**APPLICANT**

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Company	<b>Sofamor Danek USA, Inc.</b>
Location	Memphis, TN, US
Contact	RICHARD W TREHARNE, PH.D.
510(k) history	41 submissions · 26 cleared · 1995-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964159/>; 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 21, 2026