

**K971966 CORONARY VEIN GRAFT TAG MARKER**Jan 26, 1998  
243 days to decisionK971966 · Product code: **KPK** · CardiovascularSource: <https://www.510kdatabase.net/k971966/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Ostia, Aorto-saphenous Vein (KPK)
Date received	May 28, 1997
Decision date	Jan 26, 1998
Days to decision	243 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Med-Edge, Inc.</b>
Location	Clemmons, NC, US
Contact	STEVE OWENBY
510(k) history	2 submissions · 2 cleared · 1988-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971966/> 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 July 4, 2026