

**K972570 HEARTPORT INTRODUCER SHEATH**Oct 1, 1997  
83 days to decisionK972570 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k972570/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 10, 1997
Decision date	Oct 1, 1997
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heartport, Inc.</b>
Location	Redwood City, CA, US
Contact	MARIANNE C DRENNAN
510(k) history	24 submissions · 24 cleared · 1996-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972570/> 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