

**K950615 KAPLAN-SIMPSON INFUSASLEEVE CATHETER**Apr 19, 1995  
68 days to decisionK950615 · Product code: **QEY** · CardiovascularSource: <https://www.510kdatabase.net/k950615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Feb 10, 1995
Decision date	Apr 19, 1995
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Localmed, Inc.</b>
Location	Sunnyvale, CA, US
Contact	ELEANOR V CHIU
510(k) history	5 submissions · 5 cleared · 1994-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950615/> 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