

K972175 INFUSASLEEVE IIA (IS-2A)Aug 28, 1997
80 days to decisionK972175 · Product code: **QEY** · CardiovascularSource: <https://www.510kdatabase.net/k972175/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Jun 9, 1997
Decision date	Aug 28, 1997
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Localmed, Inc.
Location	Sunnyvale, CA, US
Contact	EDWIN L EE
510(k) history	5 submissions · 5 cleared · 1994-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972175/> Data sourced from FDA 510(k) public records (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. - Generated July 4, 2026