

**K943777 SCIMED 8 FRENCH BIG-MAX GUIDE CATHETER**Oct 13, 1994  
72 days to decisionK943777 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k943777/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 2, 1994
Decision date	Oct 13, 1994
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Scimed Life Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	DIANE M LOWE
510(k) history	109 submissions · 108 cleared · 1977-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943777/> 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 June 29, 2026