

K964859 SCIMED 5 FRENCH IMPULSE ANGIOGRAPHIC CATHETERSFeb 10, 1997
68 days to decisionK964859 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k964859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Dec 4, 1996
Decision date	Feb 10, 1997
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scimed Life Systems, Inc.
Location	Mchenry, IL, US
Contact	ANGELA RAUN
510(k) history	109 submissions · 108 cleared · 1977-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964859/>; 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 June 29, 2026