

**K913364 SCIMED 7 FR. & 8 FR.**Aug 30, 1991  
32 days to decisionK913364 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k913364/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jul 29, 1991
Decision date	Aug 30, 1991
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913364/> 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