FDA 510(k) Premarket Notification

K913364 SCIMED 7 FR. & 8 FR.

CLEARED

Aug 30, 1991
32 days to decision

K913364 · 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	**Scimed Life Systems, Inc.**
Location	Mchenry, IL, US
Contact	MERCEDES P BAYANI
510(k) history	109 submissions · 108 cleared · 1977-1998