FDA 510(k) Premarket Notification

K914312 SCIMED 7FR AND 8FR TRIGUIDE GUIDING CATHETERS

CLEARED

Nov 22, 1991
57 days to decision

K914312 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k914312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Sep 26, 1991
Decision date	Nov 22, 1991
Days to decision	57 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