FDA 510(k) Premarket Notification

K953265 SCIMED ANGIOGRAPHIC KITS

CLEARED

Jan 16, 1996
187 days to decision

K953265 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k953265/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jul 13, 1995
Decision date	Jan 16, 1996
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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