FDA 510(k) Premarket Notification

K970469 EVT ANGIOSCALE ANGIOGRAPHIC CATHETER

CLEARED

May 8, 1997
90 days to decision

K970469 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k970469/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Feb 7, 1997
Decision date	May 8, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Cardiac and Vascular Surgery**
Location	Menlo Park, CA, US
Contact	LUANNE TERMEER
510(k) history	7 submissions · 7 cleared · 1997-2002