FDA 510(k) Premarket Notification

K970762 DUAL LUMEN EMBOLECTOMY CATHETER

CLEARED

Mar 28, 1997
25 days to decision

K970762 · Product code: **DXE** · Cardiovascular
Source: https://www.510kdatabase.net/k970762/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Mar 3, 1997
Decision date	Mar 28, 1997
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Applied Medical Resources**
Location	Launa Hills, CA, US
Contact	HOWARD V ROWE
510(k) history	58 submissions · 58 cleared · 1992-2021