FDA 510(k) Premarket Notification

K972572 SINGLE LUMEN EMBOLECTOMY CATHETER

CLEARED

Jan 13, 1998
187 days to decision

K972572 · Product code: **DXE** · Cardiovascular
Source: https://www.510kdatabase.net/k972572/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Jul 10, 1997
Decision date	Jan 13, 1998
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**American Biomed, Inc.**
Location	Houston, TX, US
Contact	J.HARVEY KNAUSS
510(k) history	1 submissions · 1 cleared · 1998-1998