FDA 510(k) Premarket Notification

K834547 ANGIOSCOPY CATHETER

CLEARED

Jun 11, 1984
167 days to decision

K834547 · Product code: **LYK** · Cardiovascular
Source: https://www.510kdatabase.net/k834547/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Angioscope (LYK)
Date received	Dec 27, 1983
Decision date	Jun 11, 1984
Days to decision	167 days
Third-party review	No

APPLICANT

Company	**American Edwards Laboratories**
Location	Walker, MI, US
510(k) history	89 submissions · 88 cleared · 1980-1987