FDA 510(k) Premarket Notification

K834220 HYBRID PERIPHERAL DILATION CATHETER

CLEARED

Jan 27, 1984
53 days to decision

K834220 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k834220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Dec 5, 1983
Decision date	Jan 27, 1984
Days to decision	53 days
Third-party review	No

APPLICANT

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