FDA 510(k) Premarket Notification

K812935 FOGARTY FLEXIBLE PROBE

CLEARED

Nov 16, 1981
27 days to decision

K812935 · Product code: **DWP** · Cardiovascular
Source: https://www.510kdatabase.net/k812935/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, Surgical (DWP)
Date received	Oct 20, 1981
Decision date	Nov 16, 1981
Days to decision	27 days
Third-party review	No

APPLICANT

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