FDA 510(k) Premarket Notification

K820222 SWAN-GANZ VIP-CATHETER

CLEARED

Feb 12, 1982
16 days to decision

K820222 · Product code: **DYG** · Cardiovascular
Source: https://www.510kdatabase.net/k820222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Jan 27, 1982
Decision date	Feb 12, 1982
Days to decision	16 days
Third-party review	No

APPLICANT

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