FDA 510(k) Premarket Notification

K803058 SWAN-GANZ FLOW-DIRECTED MULTIPUR. CATH.

CLEARED

Jan 16, 1981
45 days to decision

K803058 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k803058/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Dec 2, 1980
Decision date	Jan 16, 1981
Days to decision	45 days
Third-party review	No

APPLICANT

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