FDA 510(k) Premarket Notification

K803270 GANZ CORONARY REPERFUSION CATHETER

CLEARED

Mar 27, 1981
88 days to decision

K803270 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k803270/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Dec 29, 1980
Decision date	Mar 27, 1981
Days to decision	88 days
Third-party review	No

APPLICANT

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