FDA 510(k) Premarket Notification

K831563 CORONARY GUIDING CATHETER-MODIFIED

CLEARED

Jun 30, 1983
45 days to decision

K831563 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k831563/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 16, 1983
Decision date	Jun 30, 1983
Days to decision	45 days
Third-party review	No

APPLICANT

Company	**Advanced Cardiovascular Systems, Inc.**
Location	Santa Clara, CA, US
510(k) history	103 submissions · 100 cleared · 1982-2002