FDA 510(k) Premarket Notification

K822393 INTRAOPERATIVE BALLOON DILATION CATH.

CLEARED

Nov 1, 1982
84 days to decision

K822393 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k822393/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 9, 1982
Decision date	Nov 1, 1982
Days to decision	84 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