FDA 510(k) Premarket Notification

K915723 .10' HI-TORQUE FLOPPY, INTER. & STAND. GUIDE WIRE

CLEARED

Jun 9, 1992
172 days to decision

K915723 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k915723/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 20, 1991
Decision date	Jun 9, 1992
Days to decision	172 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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