

K971577 FOCUS-PV BALLOON DILATATION CATHETERJun 18, 1997
58 days to decisionK971577 · Product code: LIT · Cardiovascular
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 21, 1997
Decision date	Jun 18, 1997
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular Dynamics, Inc.
Location	Irvine, CA, US
Contact	PAM MISAJON
510(k) history	11 submissions · 11 cleared · 1994-1998

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