

K952064 FOCUS BALLOON DILATATION CATHETERJun 21, 1995
50 days to decisionK952064 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k952064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 2, 1995
Decision date	Jun 21, 1995
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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