

K944016 FOCUS BALLOON DILATATION CATHETERDec 20, 1994
126 days to decisionK944016 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k944016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Aug 16, 1994
Decision date	Dec 20, 1994
Days to decision	126 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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