

**K954313 FOCUS PC BALLOON DILATATION CATHETER**Dec 1, 1995  
77 days to decisionK954313 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k954313/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Sep 15, 1995
Decision date	Dec 1, 1995
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardio-Dynamics, Inc.</b>
Location	Irvine, CA, US
Contact	MICHAEL CROCKER
510(k) history	4 submissions · 4 cleared · 1994-1995

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