

**K940547 FLOW DIRECT THERMODILUT BALLOON CATH
HEPARIN COATED**Aug 11, 1994
185 days to decisionK940547 · Product code: **DYG** · Cardiovascular
Source: <https://www.510kdatabase.net/k940547/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Feb 7, 1994
Decision date	Aug 11, 1994
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	J-Lloyd Medical, Inc.
Location	West Berlin, NJ, US
Contact	JAMES L SKAGGS
510(k) history	16 submissions · 16 cleared · 1993-1998

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