

**K963248 FLOW DIRECTED THERMODILUTION/INFUSION  
BALLOON CATHETER (575-110P)**Feb 3, 1997  
168 days to decisionK963248 · Product code: **DYG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k963248/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Aug 19, 1996
Decision date	Feb 3, 1997
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963248/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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