

**K935404 FLOW DIRECTED THERMODILUTION BALLOON
CATHETER**May 3, 1994
175 days to decisionK935404 · Product code: **DYG** · Cardiovascular
Source: <https://www.510kdatabase.net/k935404/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Flow Directed (DYG) |
| Date received | Nov 9, 1993 |
| Decision date | May 3, 1994 |
| Days to decision | 175 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935404/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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