

**K934624 ACS ROTATING HEMOSTATIC VALVE & ACS
DUOSTAT ROTATING HEMOSTATIC VALVE**Apr 13, 1994
198 days to decisionK934624 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k934624/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 27, 1993
Decision date	Apr 13, 1994
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Cardiovascular Systems, Inc.
Location	Santa Clara, CA, US
Contact	JUDITH P PALIN
510(k) history	103 submissions · 100 cleared · 1982-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934624/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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