

K981909 BAXTER HEMOSTASIS VALVE INTRODUCERSNov 24, 1998
176 days to decisionK981909 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k981909/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 1, 1998
Decision date	Nov 24, 1998
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Edwards
Location	Irvine, CA, US
Contact	SCOTT BEGGINS
510(k) history	11 submissions · 10 cleared · 1993-2000

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