

**K932208 EXTRACORPOREAL CIRCUIT W/DURAFLO II
HEPARIN TREATM**

Aug 9, 1994
460 days to decision

K932208 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k932208/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	May 6, 1993
Decision date	Aug 9, 1994
Days to decision	460 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	PAUL ZALESKY
510(k) history	505 submissions · 496 cleared · 1977-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k932208/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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