

**K941225 UNIVIX GOLD MEMBRANE OXYGENATION MODULE
WITH DUROFLO II HEPARIN TREATMENT**Aug 16, 1994
155 days to decisionK941225 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k941225/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 14, 1994
Decision date	Aug 16, 1994
Days to decision	155 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k941225/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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