

K893704 SAFE-1Dec 22, 1989
218 days to decisionK893704 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k893704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	May 18, 1989
Decision date	Dec 22, 1989
Days to decision	218 days
Third-party review	No

APPLICANT

Company	Polystan C/O Vitalcor, Inc.
Location	Ballerup Denmark, US
Contact	HENNING LARSEN
510(k) history	8 submissions · 8 cleared · 1984-1990

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