

K894657 POLYSTAN HEART-LUNG MACHINE SYSTEMMar 28, 1990
247 days to decisionK894657 · Product code: **DJQ** · Toxicology
Source: <https://www.510kdatabase.net/k894657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test Reagents For Phenothiazine (DJQ)
Date received	Jul 24, 1989
Decision date	Mar 28, 1990
Days to decision	247 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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