FDA 510(k) Premarket Notification

K912082 SAFE II

CLEARED

Dec 4, 1991
208 days to decision

K912082 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k912082/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	May 10, 1991
Decision date	Dec 4, 1991
Days to decision	208 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Polystan A/S**
Location	Denmark, DK
Contact	MOE HAVELAND
510(k) history	6 submissions · 6 cleared · 1991-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k912082/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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