

**K980974 SAFE MINI**Oct 13, 2000  
942 days to decisionK980974 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k980974/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 16, 1998
Decision date	Oct 13, 2000
Days to decision	942 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Polystan A/S</b>
Location	Denmark, DK
Contact	THOMAS ANDERSEN
510(k) history	6 submissions · 6 cleared · 1991-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980974/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026