

K953976 SAFE MICROFeb 4, 1997
531 days to decisionK953976 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k953976/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received | Aug 23, 1995 |
| Decision date | Feb 4, 1997 |
| Days to decision | 531 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953976/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026