

K874853 POLYSTAN TWO STAGE CATHETERSFeb 5, 1988
72 days to decisionK874853 · Product code: **DWF** · CardiovascularSource: <https://www.510kdatabase.net/k874853/>**SUBMISSION DETAILS**

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|-----------------------|----------------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF) |
| Date received | Nov 25, 1987 |
| Decision date | Feb 5, 1988 |
| Days to decision | 72 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k874853/>; 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 29, 2026