FDA 510(k) Premarket Notification

# K874853 POLYSTAN TWO STAGE CATHETERS

**CLEARED**

Feb 5, 1988
72 days to decision

K874853 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k874853/

## SUBMISSION DETAILS

| | |
|---|---|
| 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 |