

K974259 VENOUS FLEX II PERIPHERAL AND INTRA-OPERATIVE ACCESS VENOUS RETURN CANNULAEDec 1, 1998
383 days to decisionK974259 · Product code: DWF · Cardiovascular
Source: <https://www.510kdatabase.net/k974259/>**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 13, 1997 |
| Decision date | Dec 1, 1998 |
| Days to decision | 383 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Edwards Lifesciences Research Medical |
| Location | Midvale, UT, US |
| Contact | R D HIBBERT |
| 510(k) history | 6 submissions · 6 cleared · 1998-2008 |

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