

**K884325 SUBCLAVIAN HEMODIALYSIS CATH. W/ITACUFF
DEVICE**Apr 25, 1989
193 days to decisionK884325 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k884325/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ) |
| Date received | Oct 14, 1988 |
| Decision date | Apr 25, 1989 |
| Days to decision | 193 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Bd Becton Dickinson Vacutainer Systems Preanalytic |
| Location | Washington, DC, US |
| Contact | CHARLES J WELLE |
| 510(k) history | 632 submissions · 625 cleared · 1976-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k884325/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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