

K252137 BD Insyte™ IV CatheterApr 2, 2026
268 days to decisionK252137 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k252137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jul 8, 2025
Decision date	Apr 2, 2026
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Becton Dickinson Infusion Therapy Systems, Inc.
Location	Sandy, UT, US
Contact	Teresa Do-McCage
510(k) history	36 submissions · 36 cleared · 1997-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252137/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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