

K251654 BD Insyte™ Autoguard™ Shielded IV Catheter, BD Insyte™ Autoguard™ BC Shielded IV Catheter and BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter

Jun 27, 2025
28 days to decision

K251654 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k251654/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	May 30, 2025
Decision date	Jun 27, 2025
Days to decision	28 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	Laura Castelnoble
510(k) history	36 submissions · 36 cleared · 1997-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251654/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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