

K000235 INSYTE CATHETER, INSYTE AUTOGUARD CATHETERApr 5, 2000
69 days to decisionK000235 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k000235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jan 27, 2000
Decision date	Apr 5, 2000
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000235/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026