FDA 510(k) Premarket Notification

K000235 INSYTE CATHETER, INSYTE AUTOGUARD CATHETER

CLEARED

Apr 5, 2000
69 days to decision

K000235 · 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