FDA 510(k) Premarket Notification

K971339 INSYTE, INSYTE-W, INSYTE AUTOGUARD CATHETERS

CLEARED

Dec 24, 1997
258 days to decision

K971339 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k971339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Apr 10, 1997
Decision date	Dec 24, 1997
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Becton Dickinson Vascular Access, Inc.**
Location	Sandy, UT, US
Contact	C.J. WELLE
510(k) history	25 submissions · 22 cleared · 1992-1997