

**K991647 TFX MEDICAL INTRODUCER KIT**Jan 4, 2000  
236 days to decisionK991647 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k991647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 13, 1999
Decision date	Jan 4, 2000
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tfx Medical Group</b>
Location	Jeffrey, NH, US
Contact	JULIE A BEAUMONT
510(k) history	3 submissions · 3 cleared · 1996-2000

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