FDA 510(k) Premarket Notification

K003452 POLARIS X CATHETERS, MODEL 7000D,7001D,7003D,7004D,7005D,7006D

CLEARED

Dec 7, 2000
30 days to decision

K003452 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k003452/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Nov 7, 2000
Decision date	Dec 7, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ep Technologies, Inc.**
Location	Mountain View, CA, US
Contact	CHRISTINA ROWE
510(k) history	15 submissions · 15 cleared · 1988-2005