FDA 510(k) Premarket Notification

K022357 TRANSEND 300 ES GUIDEWIRE, MODEL 46-814 & TRANSEND 300 FLOPPY GUIDEWIRE, MODEL 46-815

CLEARED

Oct 16, 2002
89 days to decision

K022357 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k022357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jul 19, 2002
Decision date	Oct 16, 2002
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific, Target**
Location	Freemont, CA, US
Contact	GEORGE J PRENDERGAST
510(k) history	19 submissions · 19 cleared · 1999-2003