FDA 510(k) Premarket Notification

K053251 TECHDEVICE GUIDEWIRE

CLEARED

Mar 8, 2006
107 days to decision

K053251 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k053251/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 21, 2005
Decision date	Mar 8, 2006
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Techdevice Corporation**
Location	Watertown, MA, US
Contact	LEIGH HAYWARD
510(k) history	4 submissions · 4 cleared · 2006-2011