FDA 510(k) Premarket Notification

K001033 AGILITY STEERABLE GUIDEWIRE

CLEARED

Apr 14, 2000
14 days to decision

K001033 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k001033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 31, 2000
Decision date	Apr 14, 2000
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Neurovascular, Inc.**
Location	Miami Lakes, FL, US
Contact	MARITZA CELAYA
510(k) history	37 submissions · 37 cleared · 1994-2008