FDA 510(k) Premarket Notification

K955637 ESSENCE GUIDEWIRE

CLEARED

Mar 11, 1996
91 days to decision

K955637 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k955637/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 11, 1995
Decision date	Mar 11, 1996
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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