FDA 510(k) Premarket Notification

K120863 WHOLEY GUIDE WIRE SYSTEM

CLEARED

Apr 19, 2012
28 days to decision

K120863 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k120863/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 22, 2012
Decision date	Apr 19, 2012
Days to decision	28 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Covidien, LLC**
Location	Mansfield, MA, US
Contact	DAVID RBERTSON
510(k) history	89 submissions · 86 cleared · 2010-2026