FDA 510(k) Premarket Notification

K130378 RESPIGUIDE DELIVERY SYSTEM

CLEARED

Oct 17, 2013
245 days to decision

K130378 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k130378/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 14, 2013
Decision date	Oct 17, 2013
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Respicardia**
Location	Minnetonka, MN, US
Contact	BONNIE LABOSKY
510(k) history	1 submissions · 1 cleared · 2013-2013