FDA 510(k) Premarket Notification

K131492 MODIFIED FLOWGATE BALLOON GUIDE CATHETER

CLEARED

Oct 3, 2013
133 days to decision

K131492 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k131492/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 23, 2013
Decision date	Oct 3, 2013
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Concentric Medical, Inc.**
Location	Moutian View, CA, US
Contact	RHODA SANTOS
510(k) history	45 submissions · 44 cleared · 2001-2018