FDA 510(k) Premarket Notification

K133177 MODIFIED HD GUIDE CATHETER

CLEARED

Feb 25, 2014
131 days to decision

K133177 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k133177/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 17, 2013
Decision date	Feb 25, 2014
Days to decision	131 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