

**K122581 MODIFIED BALLOON GUIDE CATHETER MODEL
90253, 90254**Nov 21, 2012
90 days to decisionK122581 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k122581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 23, 2012
Decision date	Nov 21, 2012
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122581/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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