

K153729 8F FlowGate2 Balloon Guide CatheterJan 27, 2016
30 days to decisionK153729 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k153729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 28, 2015
Decision date	Jan 27, 2016
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Concentric Medical
Location	Mountain View, CA, US
Contact	SHAZIA HAKIM
510(k) history	1 submissions · 1 cleared · 2016-2016

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