

**K133074 MEGA 8FR. 50CC AND SENSATION PLUS 8FR. 50CC
INTRA-AORTIC BALLOON CATHETERS AND ACCESSORIES**Dec 12, 2013
73 days to decisionK133074 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k133074/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Sep 30, 2013
Decision date	Dec 12, 2013
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Datascope Corp.
Location	Mchenry, IL, US
Contact	LINDA SLUTZKY
510(k) history	136 submissions · 135 cleared · 1976-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133074/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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