

**K122628 SENSATION PLUS 7.5FR. 40CC INTRA-AORTIC
BALLOON (IAB) CATHETER AND ACCESSORIES**Sep 6, 2012
9 days to decisionK122628 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k122628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Aug 28, 2012
Decision date	Sep 6, 2012
Days to decision	9 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Datascope Corp., Cardiac Assist Division
Location	Fairfield, NJ, US
Contact	CARLA S CERQUEIRA
510(k) history	4 submissions · 4 cleared · 2009-2012

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