

**K120868 MEGA(TM) 7.5FR. 30CC INTRA-AORTIC BALLOON CATHETER AND ACCESSORIES, MEGA(TM) 7.5FR. 40CC INTRA-AORTIC BALLOON CATHETER**Apr 20, 2012  
29 days to decisionK120868 · Product code: **DSP** · Cardiovascular  
Source: <https://www.510kdatabase.net/k120868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Mar 22, 2012
Decision date	Apr 20, 2012
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Datascope Corp., Cardiac Assist Division</b>
Location	Fairfield, NJ, US
Contact	HELDER A SOUSA
510(k) history	4 submissions · 4 cleared · 2009-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120868/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 20, 2026