

**K980385 DATASCOPE 8FR. CO-LUMEN 34 AND 40CC INTRA-AORTIC BALLOON CATHETERS FOR OPTIONAL SHEATHLESS INSERTION WITH ACCESSORIES**May 1, 1998  
88 days to decisionK980385 · Product code: **DSP** · Cardiovascular  
Source: <https://www.510kdatabase.net/k980385/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Feb 2, 1998
Decision date	May 1, 1998
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Datascope Corp.</b>
Location	Mchenry, IL, US
Contact	WHITNEY TORNING
510(k) history	136 submissions · 135 cleared · 1976-2019

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