

**K013326 MODIFICATION TO: DATASCOPE 8FR. POLYIMIDE
ALT B IAB, 25CC, 34CC, 40CC, DATASCOPE INSERTION KIT
FOR 8 FR, POLYIMIDE ALT B**Nov 2, 2001
28 days to decisionK013326 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k013326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Oct 5, 2001
Decision date	Nov 2, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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