

**K994157 DATASCOPE'S 8FR. POLYIMIDE 25CC,34CC
AND 40CC IAB AND ACCESSORIES, MODELS 0684-00-0327,
06844-00-0328, 0684-00-0329**Mar 13, 2000
95 days to decisionK994157 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k994157/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Dec 9, 1999
Decision date	Mar 13, 2000
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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