

**K003598 DATASCOPE PROFILE 8FR. ALT B IAB, 34CC,
 DATASCOPE PROFILE 8FR. ALT B IAB, 40CC, MODEL
 0684-000319, 0684-00-0320**

Dec 21, 2000
 30 days to decision

K003598 · Product code: **DSP** · Cardiovascular
 Source: <https://www.510kdatabase.net/k003598/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Nov 21, 2000
Decision date	Dec 21, 2000
Days to decision	30 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k003598/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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