

K821065 DATASCOPE 10.5 FRENCH INTRA-AORTIC BALAug 19, 1982
126 days to decisionK821065 · Product code: **DSP** · CardiovascularSource: <https://www.510kdatabase.net/k821065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Apr 15, 1982
Decision date	Aug 19, 1982
Days to decision	126 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k821065/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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