

**K921638 SYSTEM 90 INTRA-AORTIC BALLOON PUMP
CONSOLE**Feb 10, 1993
310 days to decisionK921638 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k921638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Apr 6, 1992
Decision date	Feb 10, 1993
Days to decision	310 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k921638/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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