

K944460 DATASCOPE INTRA-AORTIC BALLOON WITH MODIFIED STAT GARD

Dec 9, 1994
88 days to decision

K944460 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k944460/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Sep 12, 1994
Decision date	Dec 9, 1994
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k944460/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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