

K912629 DATASCOPE SYSTEM 95Mar 11, 1992
268 days to decisionK912629 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k912629/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Balloon, Intra-aortic And Control (DSP) |
| Date received | Jun 17, 1991 |
| Decision date | Mar 11, 1992 |
| Days to decision | 268 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 |

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