

**K091449 DATASCOPE'S 8FR. 50CC INTRA-AORTIC
BALLOON CATHETER AND ACCESSORIES, MODELS
0684,00-0498-01, 02**Jun 18, 2009
31 days to decisionK091449 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k091449/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Balloon, Intra-aortic And Control (DSP) |
| Date received | May 18, 2009 |
| Decision date | Jun 18, 2009 |
| Days to decision | 31 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Datascope Corp., Cardiac Assist Division |
| Location | Fairfield, NJ, US |
| Contact | DOLLY MISTRY |
| 510(k) history | 4 submissions · 4 cleared · 2009-2012 |

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