

K983135 BLOWER/MISTERNov 13, 1998
66 days to decisionK983135 · Product code: **FQH** · General Hospital
Source: <https://www.510kdatabase.net/k983135/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lavage, Jet (FQH) |
| Date received | Sep 8, 1998 |
| Decision date | Nov 13, 1998 |
| Days to decision | 66 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cardiothoracic Systems, Inc. |
| Location | Cupertino, CA, US |
| Contact | MIKE BILLIG |
| 510(k) history | 8 submissions · 8 cleared · 1997-2001 |

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