

**K073712 SOFT AIR, MODEL SA 4000 AND MISTRAL AIR,  
MODEL MA0100**Jun 6, 2008  
158 days to decisionK073712 · Product code: **DWJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k073712/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, Thermal Regulating (DWJ)   |
| Date received         | Dec 31, 2007                       |
| Decision date         | Jun 6, 2008                        |
| Days to decision      | 158 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Adroit Medical Systems, Inc.</b>   |
| Location       | Morganton, NC, US                     |
| Contact        | JON R HERMANSON                       |
| 510(k) history | 6 submissions · 6 cleared · 1992-2008 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073712/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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