

**K943106 ADULT VENTILATOR**Dec 28, 1995  
547 days to decisionK943106 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k943106/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent - ST              |
| Submission type       | Traditional                                |
| Device classification | Ventilator, Continuous, Facility Use (CBK) |
| Date received         | Jun 29, 1994                               |
| Decision date         | Dec 28, 1995                               |
| Days to decision      | 547 days                                   |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Infrasonics Corp.</b>                |
| Location       | Walker, MI, US                          |
| Contact        | JIM HITCHIN                             |
| 510(k) history | 20 submissions · 19 cleared · 1984-1995 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943106/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026