

**K954150 VENTILATOR, EMERGENCY, MANUAL  
(RESUSCITATOR)**Dec 20, 1995  
106 days to decisionK954150 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k954150/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | Ventilator, Emergency, Manual (resuscitator) (BTM) |
| Date received         | Sep 5, 1995  |
| Decision date         | Dec 20, 1995                                       |
| Days to decision      | 106 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Green Field Medical Sourcing, Inc.</b> |
| Location       | Northborough, MA, US                      |
| Contact        | BRIAN SWANSON                             |
| 510(k) history | 5 submissions · 5 cleared · 1994-1998     |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954150/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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