

**K991953 MODIFICATION TO ENGINEERED MEDICAL SYSTEMS  
DISPOSABLE MANUAL RESUSCITATOR WITH CO2  
DETECTION**Jul 1, 1999  
30 days to decisionK991953 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k991953/>**SUBMISSION DETAILS**

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|                       |                                                    |
|-----------------------|----------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional                                        |
| Device classification | Ventilator, Emergency, Manual (resuscitator) (BTM) |
| Date received         | Jun 1, 1999                                        |
| Decision date         | Jul 1, 1999                                        |
| Days to decision      | 30 days                                            |
| Third-party review    | No                                                 |
| Summary / Statement   | Summary                                            |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Engineered Medical Systems</b>       |
| Location       | Indianapolis, IN, US                    |
| Contact        | BONNIE HOLLY                            |
| 510(k) history | 22 submissions · 22 cleared · 1987-2003 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991953/> 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 25, 2026