

**K991955 MODIFICATION TO ENGINEERED MEDICAL SYSTEMS  
DISPOSABLE MANUAL RESUSCITATOR WITH CO2  
DETECTION**Jul 6, 1999  
35 days to decisionK991955 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k991955/>**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 6, 1999
Days to decision	35 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/k991955/> 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