

**K970991 DATEX ENGSTOM MANUAL RESUSCITATOR**Jun 16, 1997  
89 days to decisionK970991 · Product code: **BTM** · AnesthesiologySource: <https://www.510kdatabase.net/k970991/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Mar 19, 1997
Decision date	Jun 16, 1997
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Promedic, Inc.</b>
Location	Indianapolis, IN, US
Contact	PAUL E DRYDEN
510(k) history	16 submissions · 14 cleared · 1995-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970991/> 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