

**K014115 1ST RESPONSE MANUAL RESUSCITATOR, MODEL 85XX**Feb 27, 2002  
75 days to decisionK014115 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k014115/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Dec 14, 2001
Decision date	Feb 27, 2002
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Portex, Inc.</b>
Location	Walker, MI, US
Contact	TIMOTHY J TALCOTT
510(k) history	20 submissions · 20 cleared · 1977-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k014115/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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