

**K991861 1ST RESPONSE INFANT MANUAL RESUSCITATOR,  
BAG RESEVOIR, 1ST RESPONSE PEDIATRIC MANUAL  
RESUSCITATOR, BAG RESERVOIR, 1ST RE**

Jan 18, 2000  
231 days to decision

K991861 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k991861/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jun 1, 1999
Decision date	Jan 18, 2000
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sims Portex, Inc.</b>
Location	Keene, NH, US
Contact	TIMOTHY J TALCOTT
510(k) history	12 submissions · 12 cleared · 1998-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k991861/> 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