

**K964584 AMBU SPUR NEONATE**May 15, 1997  
181 days to decisionK964584 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k964584/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Nov 15, 1996
Decision date	May 15, 1997
Days to decision	181 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Ambu, Inc.</b>
Location	Walker, MI, US
Contact	SANJAY H PARIKH
510(k) history	33 submissions · 33 cleared · 1984-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964584/> 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