

K042843 AMBU SPUR II INFANT AND PEDIATRIC SINGLE PATIENT USE RESUSCITATORSNov 12, 2004
29 days to decisionK042843 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k042843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Oct 14, 2004
Decision date	Nov 12, 2004
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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