

K993278 AMBU NEONATE SILICONE RESUSCITATORMay 17, 2000
230 days to decisionK993278 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k993278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Sep 30, 1999
Decision date	May 17, 2000
Days to decision	230 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

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