

K894365 SINGLE PATIENT USE DISPOSABLE MANUAL RESUSCITATOROct 6, 1989
84 days to decisionK894365 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k894365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jul 14, 1989
Decision date	Oct 6, 1989
Days to decision	84 days
Third-party review	No

APPLICANT

Company	Puritan Bennett Corp.
Location	Mchenry, IL, US
Contact	MARSHALL SMITH
510(k) history	110 submissions · 101 cleared · 1976-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894365/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026