

**K935784 PURITAN-BENNETT COMPANION 320 I/E BI-LEVEL
RESPIRATORY SYSTEM**Jul 13, 1994
219 days to decisionK935784 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k935784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 6, 1993
Decision date	Jul 13, 1994
Days to decision	219 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Puritan-Bennett
Location	Lenexa, KS, US
Contact	C. MARSHALL SMITH
510(k) history	4 submissions · 3 cleared · 1994-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935784/> 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