

K012271 ACUTEVENTILATOROct 4, 2002
442 days to decisionK012271 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k012271/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jul 19, 2001
Decision date	Oct 4, 2002
Days to decision	442 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Impoex International, Ltd.
Location	Little River, SC, US
Contact	SIVERT CLAEISSON
510(k) history	1 submissions · 1 cleared · 2002-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012271/> 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