FDA 510(k) Premarket Notification

K012842 V*CARE MANUAL RESUSCITATOR

CLEARED

Sep 18, 2001
26 days to decision

K012842 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k012842/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Aug 23, 2001
Decision date	Sep 18, 2001
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ventlab Corp.**
Location	Hackensack, NJ, US
Contact	MARGE WALLS-WALKER
510(k) history	22 submissions · 22 cleared · 1989-2012