FDA 510(k) Premarket Notification

K013308 VENTLAB HYPERINFLATION BAG SYSTEM

CLEARED

Dec 20, 2001
77 days to decision

K013308 · Product code: **NHK** · Anesthesiology
Source: https://www.510kdatabase.net/k013308/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resuscitator, Manual, Non Self-inflating (NHK)
Date received	Oct 4, 2001
Decision date	Dec 20, 2001
Days to decision	77 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