FDA 510(k) Premarket Notification

K923976 AMBU SINGLE PATIENT USE PEEP VALVE

CLEARED

Jan 5, 1993
151 days to decision

K923976 · Product code: **BYE** · Anesthesiology
Source: https://www.510kdatabase.net/k923976/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Attachment, Breathing, Positive End Expiratory Pressure (BYE)
Date received	Aug 7, 1992
Decision date	Jan 5, 1993
Days to decision	151 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ambu, Inc.**
Location	Walker, MI, US
Contact	DAVID LEE
510(k) history	33 submissions · 33 cleared · 1984-2005