FDA 510(k) Premarket Notification

CLEARED

K042682 AMBU SPUR II. ADULT SINGLE PATIENT RESUSCITATOR

Nov 15, 2004
47 days to decision

K042682 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k042682/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Sep 29, 2004
Decision date	Nov 15, 2004
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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