FDA 510(k) Premarket Notification

CLEARED

K152931 Ambu SPUR II Adult Resuscitator, Ambu SPUR II Pediatric Resuscitator, Ambu SPUR II Infant Resuscitator

Aug 29, 2016
329 days to decision

K152931 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k152931/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Oct 5, 2015
Decision date	Aug 29, 2016
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ambu A/S**
Location	Glen Burnie, MD, US
Contact	LINE KAGENOW SVENSTRUP
Website	https://www.ambu.com
510(k) history	38 submissions · 38 cleared · 2005-2026

Ambu A/S is a global medical device company specializing in single-use endoscopy and airway management solutions. The company operates with a manufacturing facility in Glen Burnie, Maryland, and serves hospitals and emergency care settings worldwide. Ambu created the single-use endoscopy market in 2009 and remains the market leader in this category. Ambu has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory activity spans from 2005 to 2026, demonstrating sustained innovation and market presence. Recent cl...