

K102824 AMBU OVAL SILICONE RESUSCITATOR, ADULT AND PEDIATRICJan 28, 2011
121 days to decisionK102824 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k102824/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Sep 29, 2010
Decision date	Jan 28, 2011
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ambu A/S
Location	Glen Burnie, MD, US
Contact	SANJAY PARIKH
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...