FDA 510(k) Premarket Notification

K130845 AMBU ASCOPE 3 5.0/2.2

CLEARED

Nov 1, 2013
220 days to decision

K130845 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k130845/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Mar 26, 2013
Decision date	Nov 1, 2013
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary
Other names	AMBU ASCOPE 3 SLIM 3.8/1.2; AMBU AVIEW

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...

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Device record: https://www.510kdatabase.net/k130845/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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