FDA 510(k) Premarket Notification

CLEARED

K173727 Ambu aScope 3 Slim 3.8/1.2 and Ambu aScope 4 Broncho Slim 3.8/1.2

Mar 28, 2018
113 days to decision

K173727 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k173727/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Dec 5, 2017
Decision date	Mar 28, 2018
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary
Other names	Ambu aScope 3 Regular 5.0/2.2 and Ambu aScope 4 Broncho Regular 5.0/2.2; Ambu aScope 3 Large 5.8/2.8 and Ambu aScope 4 Broncho Large 5.8/2.8; Ambu aView Monitor

APPLICANT

Company	**Ambu A/S**
Location	Glen Burnie, MD, US
Contact	Maja Brons
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...