

**K190972 Ambu aScope 4 RhinoLaryngo Intervention**Jul 12, 2019  
88 days to decisionK190972 · Product code: **EOB** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k190972/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nasopharyngoscope (flexible Or Rigid) (EOB)
Date received	Apr 15, 2019
Decision date	Jul 12, 2019
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ambu A/S</b>
Location	Glen Burnie, MD, US
Contact	Gurpreet Kaur Rehal
Website	<a href="https://www.ambu.com">https://www.ambu.com</a>
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...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ambu, Inc.</b>
Contact	Sanjay Parikh

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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