

**K160766 Ambu USR, Ambu M**Aug 17, 2016  
149 days to decisionK160766 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k160766/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Mar 21, 2016
Decision date	Aug 17, 2016
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ambu A/S</b>
Location	Glen Burnie, MD, US
Contact	CAMILLA WISMAR
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...

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