

**K242108 Ambu® aScope™ 5 Uretero (Standard Deflection)**Aug 16, 2024  
29 days to decisionK242108 · Product code: **FGB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k242108/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jul 18, 2024
Decision date	Aug 16, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Ambu® aScope™ 5 Uretero (Reverse Deflection); Ambu® aView™ 2 Advance

**APPLICANT**

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Company	<b>Ambu A/S</b>
Location	Glen Burnie, MD, US
Contact	Gamze Yilan
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k242108/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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