FDA 510(k) Premarket Notification

K233886 Ambu® aScope™ Duodeno 2, Ambu® aBox™ 2

CLEARED

Apr 16, 2024
130 days to decision

K233886 · Product code: **FDT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k233886/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Dec 8, 2023
Decision date	Apr 16, 2024
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ambu A/S**
Location	Glen Burnie, MD, US
Contact	Mette Andersen
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...

REGULATORY CONSULTANT

Consulting firm	**Ambu, Inc.**
Contact	Sanjay Parikh

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