

**K100129 AMBU BLUE SENSOR NEO, AMBU BLUE SENSOR NEO X**Jun 11, 2010  
143 days to decisionK100129 · Product code: **DRX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k100129/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Jan 19, 2010
Decision date	Jun 11, 2010
Days to decision	143 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	SANJAY PARIKH
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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Device record: <https://www.510kdatabase.net/k100129/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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