K071186 MODIFICATION TO: AMBU NEUROLINE CONCENTRIC NEEDLE ELECTRODE

CLEARED

Jul 30, 2007
91 days to decision

K071186 · Product code: **IKT** · Neurology
Source: https://www.510kdatabase.net/k071186/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle, Diagnostic Electromyograph (IKT)
Date received	Apr 30, 2007
Decision date	Jul 30, 2007
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ambu A/S**
Location	Glen Burnie, MD, US
Contact	SANJAY PARIKH
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...