CLEARED

Jul 14, 2026
144 days to decision

K260578 Ambu® NeurolineTM Cup MRI/CT (Models 72704/21US, 72704/23US, 72704/25US, 72704/27US) Ambu® NeurolineTM Cup MRI/CT-set (Models 72704/21-1010US, 72704/21-1010US, 72704/23-1010US, 72704/25-1010US, 72704/27-1010US) Ambu® NeurolineTM Cup MRI/CT-mini set (Models 72704/21-0301US, 72704/23-0301US, 72704/25-0301US, 72704/27-0301US)

K260578 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k260578/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Feb 20, 2026
Decision date	Jul 14, 2026
Days to decision	144 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	Lenka Vaculciakova
Website	https://www.ambu.com
510(k) history	39 submissions · 39 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