FDA 510(k) Premarket Notification

K032278 AMBU NEUROLINE SINGLE PATIENT EEG/EP CUP ELECTRODE

CLEARED

Mar 5, 2004
225 days to decision

K032278 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k032278/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Jul 24, 2003
Decision date	Mar 5, 2004
Days to decision	225 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ambu, Inc.**
Location	Walker, MI, US
Contact	SANJAY PARIKH
510(k) history	33 submissions · 33 cleared · 1984-2005

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k032278/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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