FDA 510(k) Premarket Notification

K121483 REUSABLE CUTANEOUS ELECTRODE

CLEARED

Oct 15, 2012
150 days to decision

K121483 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k121483/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	May 18, 2012
Decision date	Oct 15, 2012
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ampcare, LLC**
Location	Richardson, TX, US
Contact	DIANE RUTHERFORD
510(k) history	2 submissions · 2 cleared · 2012-2013