FDA 510(k) Premarket Notification

K123915 DE48-PLUS

CLEARED

Apr 24, 2013
126 days to decision

K123915 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k123915/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Dec 19, 2012
Decision date	Apr 24, 2013
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Grass Technologies, an Astro-Med, Inc. Product Gro**
Location	Rockland, MA, US
Contact	PHILLIP SOARES
510(k) history	1 submissions · 1 cleared · 2013-2013