FDA 510(k) Premarket Notification

K151576 Neon EEG

CLEARED

Sep 29, 2015
110 days to decision

K151576 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k151576/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Jun 11, 2015
Decision date	Sep 29, 2015
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Incereb, Ltd.**
Location	Dublin, IE
Contact	PAUL PHILLIPS
510(k) history	1 submissions · 1 cleared · 2015-2015