FDA 510(k) Premarket Notification

K113375 ESWALLOW USA ELECTRODE,ESWALLOW USA LEADWIRE

CLEARED

Jan 25, 2013
436 days to decision

K113375 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k113375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Nov 16, 2011
Decision date	Jan 25, 2013
Days to decision	436 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eswallow USA**
Location	Naples, FL, US
Contact	WILLIAM INGRAM
510(k) history	2 submissions · 2 cleared · 2011-2013