

**K113375 ESWALLOW USA ELECTRODE,ESWALLOW USA
LEADWIRE**Jan 25, 2013
436 days to decisionK113375 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113375/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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