

**K082629 S12X WITH ESAX OPTION**Jul 1, 2009  
295 days to decisionK082629 · Product code: **GYC** · Neurology  
Source: <https://www.510kdatabase.net/k082629/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cortical (GYC)
Date received	Sep 9, 2008
Decision date	Jul 1, 2009
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chatten Associates, Inc.</b>
Location	West Conshohocken, PA, US
Contact	JOHN B CHATTEN
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082629/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 22, 2026