

**K162891 Complete Control System**Apr 14, 2017  
179 days to decisionK162891 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k162891/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Oct 17, 2016
Decision date	Apr 14, 2017
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coapt, LLC</b>
Location	Chicago, IL, US
Contact	Blair Lock
510(k) history	3 submissions · 3 cleared · 2017-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162891/> 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 28, 2026