

**K222252 Self-adhesive Electrode**Jan 19, 2023  
176 days to decisionK222252 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k222252/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Jul 27, 2022
Decision date	Jan 19, 2023
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Roundwhale Technology Co. , Ltd.</b>
Location	Shenzhen, CN
Contact	Zeng Chunming
510(k) history	7 submissions · 7 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222252/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026