

**K213879 Self-adhesive Electrode**Jan 5, 2022  
23 days to decisionK213879 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k213879/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Dec 13, 2021
Decision date	Jan 5, 2022
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bozhou Rongjian Medical Appliance Co., Ltd.</b>
Location	Bozhou, CN
Contact	Zhifang Wu
510(k) history	4 submissions · 4 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai CV Technology Co., Ltd.</b>
Contact	Doris Dong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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