

**K240668 Amydi-med Disposable Non-invasive EEG electrodes**Mar 19, 2024  
11 days to decisionK240668 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k240668/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Electrode, Cutaneous (GXY)         |
| Date received         | Mar 8, 2024                        |
| Decision date         | Mar 19, 2024                       |
| Days to decision      | 11 days                            |
| Third-party review    | Yes                                |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Shenzhen Amydi-Med Electrics Tech Co., Ltd.</b> |
| Location       | Shenzhen, CN                                       |
| Contact        | Cuifang Yuan                                       |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024              |

**REGULATORY CONSULTANT**

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|-----------------|--------------------------------------|
| Consulting firm | <b>Third Party Review Group, LLC</b> |
| Contact         | Dave Yungvirt                        |

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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