

**K252439 Tutamen Self Adhesive Electrodes**May 1, 2026  
270 days to decisionK252439 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k252439/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Electrode, Cutaneous (GXY)         |
| Date received         | Aug 4, 2025                        |
| Decision date         | May 1, 2026                        |
| Days to decision      | 270 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dongguan Tutamen Metalwork Co., Ltd.</b> |
| Location       | Dongguan, CN                                |
| Contact        | Stephen Prior                               |
| 510(k) history | 2 submissions · 2 cleared · 2024-2026       |

**REGULATORY CONSULTANT**

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|-----------------|-------------------------------------|
| Consulting firm | <b>Medical Devices Pathway, LLC</b> |
| Contact         | Caitlyn Dzhafarov                   |

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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