

K180865 ZMI Self-Adhesive ElectrodesJun 28, 2018
87 days to decisionK180865 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k180865/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Cutaneous (GXY) |
| Date received | Apr 2, 2018 |
| Decision date | Jun 28, 2018 |
| Days to decision | 87 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Zmi Electronics , Ltd. |
| Location | Kaohsiung, TW |
| Contact | Wayne Chen |
| 510(k) history | 3 submissions · 3 cleared · 2018-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180865/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026