

K192568 Jiajian Self-Adhesive ElectrodeFeb 3, 2021
504 days to decisionK192568 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k192568/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Electrode, Cutaneous (GXY) |
| Date received | Sep 18, 2019 |
| Decision date | Feb 3, 2021 |
| Days to decision | 504 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Wuxi Jiajian Medical Instrument Co., Ltd. |
| Location | Wuxi, CN |
| Contact | Caihong Sun |
| 510(k) history | 12 submissions · 12 cleared · 2009-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192568/> 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 25, 2026