

K211839 Electrode Market Disposable Surface ElectrodesJul 28, 2021
44 days to decisionK211839 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k211839/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Cutaneous (GXY) |
| Date received | Jun 14, 2021 |
| Decision date | Jul 28, 2021 |
| Days to decision | 44 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Electrode Market Co., Ltd. |
| Location | Ansan-Si, KR |
| Contact | Seolmin Jeong |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211839/> 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