

K983964 BATCH #6060 CONDUCTIVE GELDec 9, 1998
33 days to decisionK983964 · Product code: **GYB** · Neurology
Source: <https://www.510kdatabase.net/k983964/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Media, Electroconductive (GYB) |
| Date received | Nov 6, 1998 |
| Decision date | Dec 9, 1998 |
| Days to decision | 33 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Skylark Device Co., Ltd. |
| Location | Taipei, Taiwan, R.O.C., TW |
| Contact | GEORGE CHEN |
| 510(k) history | 20 submissions · 20 cleared · 1991-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983964/> 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 June 29, 2026