

**K963729 SD-610M(ALSO KNOWN AS STANDARD TENS,  
SD-609M,SD-611M, GLC-I STANDARD)**Feb 13, 1997  
150 days to decisionK963729 · Product code: **GZJ** · Neurology  
Source: <https://www.510kdatabase.net/k963729/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                       |
| Submission type       | Traditional  |
| Device classification | Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ) |
| Date received         | Sep 16, 1996   |
| Decision date         | Feb 13, 1997   |
| Days to decision      | 150 days   |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963729/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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