

**K923935 SD-605 SD II PROGRAM**Oct 15, 1992  
71 days to decisionK923935 · Product code: **GZJ** · Neurology  
Source: <https://www.510kdatabase.net/k923935/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Aug 5, 1992
Decision date	Oct 15, 1992
Days to decision	71 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	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/k923935/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026