

**K964437 GB-1002 TENS WITH MASSAGE**Aug 14, 1998  
647 days to decisionK964437 · Product code: **GZJ** · Neurology  
Source: <https://www.510kdatabase.net/k964437/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Nov 5, 1996
Decision date	Aug 14, 1998
Days to decision	647 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 K 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/k964437/> 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