

**K964434 SD-970EMS ELECTRICAL MUSCULAR STIMULATOR**Oct 9, 1997  
338 days to decisionK964434 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k964434/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Nov 5, 1996
Decision date	Oct 9, 1997
Days to decision	338 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.C. 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/k964434/> 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