

**K881424 PREMIER 10S (TENS)**Apr 11, 1988  
6 days to decisionK881424 · Product code: **GZJ** · Neurology  
Source: <https://www.510kdatabase.net/k881424/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Apr 5, 1988
Decision date	Apr 11, 1988
Days to decision	6 days
Third-party review	No

**APPLICANT**

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Company	<b>American Imex</b>
Location	Irvine, CA, US
Contact	JOAN FONG
510(k) history	11 submissions · 11 cleared · 1986-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k881424/>; 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 30, 2026