

**K010615 CYCLOTEC AMT CTI TENS DEVICE**Oct 12, 2001  
225 days to decisionK010615 · Product code: **GZJ** · Neurology  
Source: <https://www.510kdatabase.net/k010615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Mar 1, 2001
Decision date	Oct 12, 2001
Days to decision	225 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cyclotec</b>
Location	Lauderhill, FL, US
Contact	STEPHEN A MICHELSON
510(k) history	1 submissions · 1 cleared · 2001-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010615/> 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