

**K111654 FD TENS 2070**Mar 1, 2012  
262 days to decisionK111654 · Product code: **GZJ** · Neurology  
Source: <https://www.510kdatabase.net/k111654/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Jun 13, 2011
Decision date	Mar 1, 2012
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fuji Dynamics , Ltd.</b>
Location	Hong Kong, CN
Contact	CHING KONG (FELIX) LEE
510(k) history	5 submissions · 5 cleared · 2011-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111654/> 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 2, 2026