

**K161349 Everyway Incontinence Stimulation System**Jul 7, 2017  
417 days to decisionK161349 · Product code: **KPI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k161349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	May 16, 2016
Decision date	Jul 7, 2017
Days to decision	417 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Everyway Medical Instrument Co., Ltd.</b>
Location	Shenkeng District, New Taipei City, CN
Contact	ROBERT TU
510(k) history	2 submissions · 2 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161349/> 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 1, 2026