

**K171430 Incontinence Treatment Device, Model LT2061**Mar 15, 2018  
304 days to decisionK171430 · Product code: **KPI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k171430/>**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 15, 2017
Decision date	Mar 15, 2018
Days to decision	304 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shenzhen Dongdixin Technology Co., Ltd.</b>
Location	Shanghai, CN
Contact	Truman Shen
510(k) history	25 submissions · 25 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171430/> 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 May 14, 2026