FDA 510(k) Premarket Notification

# K171430 Incontinence Treatment Device, Model LT2061

**CLEARED**

Mar 15, 2018
304 days to decision

K171430 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k171430/

## SUBMISSION DETAILS

| | |
|---|---|
| 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

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