FDA 510(k) Premarket Notification

K161349 Everyway Incontinence Stimulation System

CLEARED

Jul 7, 2017
417 days to decision

K161349 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k161349/

SUBMISSION DETAILS

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

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