FDA 510(k) Premarket Notification

K213116 Everyway Incontinence Stimulation System

CLEARED

Dec 3, 2021
67 days to decision

K213116 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k213116/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Sep 27, 2021
Decision date	Dec 3, 2021
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Everyway Medical Instruments Co.,Ltd**
Location	Taipei Hsien,, TW
Contact	Paul Hung
510(k) history	29 submissions · 29 cleared · 2001-2025