FDA 510(k) Premarket Notification

CLEARED

K202317 Li-Battery powered OTC TENS/EMS, model EV-804, model EV-805, & model EV-806

Nov 13, 2020
88 days to decision

K202317 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k202317/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Aug 17, 2020
Decision date	Nov 13, 2020
Days to decision	88 days
Third-party review	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