FDA 510(k) Premarket Notification

CLEARED

K230443 TENS & EMS Device (LY-ET-01, LY-ET-02, LY-ET-04)

May 22, 2023
90 days to decision

K230443 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k230443/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Feb 21, 2023
Decision date	May 22, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jiangxi Royall Smart Technology Co., Ltd.**
Location	Ganzhou, CN
Contact	Shunzhou Yang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Share Info (Guangzhou) Medical Consultant , Ltd.**
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov