FDA 510(k) Premarket Notification

K202866 TENS & EMS Device

CLEARED

May 19, 2021
233 days to decision

K202866 · Product code: **NUH** · Physical Medicine
Source: https://www.510kdatabase.net/k202866/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 28, 2020
Decision date	May 19, 2021
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Jian Feng Electronic Technology Co., Ltd.**
Location	Baoan District, Shenzhen City, CN
Contact	Feng Wen
510(k) history	4 submissions · 4 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Intertek Testing Services Shenzhen Ltd. Guangzhou.**
Contact	Iris Lin

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202866/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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