

K221384 Heating TENS/EMS Device, FT-240-1, Heating TENS/EMS Device, FT-240-2Jun 11, 2022
29 days to decisionK221384 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k221384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	May 13, 2022
Decision date	Jun 11, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hivox Biotek, Inc.
Location	Taipei, TW
Contact	Aaron Huang
510(k) history	17 submissions · 17 cleared · 2002-2024

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