

K232675 Heating Tens, FT-615Oct 5, 2023
34 days to decisionK232675 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k232675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 1, 2023
Decision date	Oct 5, 2023
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232675/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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