

K223308 HEATING TENS/EMS, FT-810RMay 13, 2023
197 days to decisionK223308 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k223308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Oct 28, 2022
Decision date	May 13, 2023
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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