

K260425 TENS / EMS DEVICE (FT-247 Series) (FT-247, FT-237)Jun 16, 2026
126 days to decisionK260425 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k260425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Feb 10, 2026
Decision date	Jun 16, 2026
Days to decision	126 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hivox Biotek, Inc.
Location	Taipei, TW
Contact	Adam Huang
510(k) history	18 submissions · 18 cleared · 2002-2026

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