

K211403 HIVOX OTC Electrical Stimulator, FT610-BOct 15, 2021
162 days to decisionK211403 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k211403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	May 6, 2021
Decision date	Oct 15, 2021
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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