

K203574 HIVOX OTC Electrical Stimulator, EM59-I, HIVOX OTC Electrical Stimulator, EM59-2Mar 10, 2021
93 days to decisionK203574 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k203574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Dec 7, 2020
Decision date	Mar 10, 2021
Days to decision	93 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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