

K212918 Heat StimPlusDec 13, 2021
90 days to decisionK212918 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k212918/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 14, 2021
Decision date	Dec 13, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Famidoc Technology Co., Ltd.
Location	Schenzhen, Guangdong, CN
Contact	Amos Zou
510(k) history	6 submissions · 6 cleared · 2005-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212918/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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