

K231423 Combo Electrotherapy Device (Models: R-C101C, R-C101D, R-C101F, R-C101G, F100, MINI-TENS-COMB, RC101I, TENS3500)Jan 22, 2024
250 days to decisionK231423 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k231423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	May 17, 2023
Decision date	Jan 22, 2024
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Roundwhale Technology Co. , Ltd.
Location	Shenzhen, CN
Contact	Zeng Chunming
510(k) history	7 submissions · 7 cleared · 2018-2024

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