

K230164 TENS and EMS Stimulation (OTC)Apr 10, 2023
80 days to decisionK230164 · Product code: **NUH** · Physical MedicineSource: <https://www.510kdatabase.net/k230164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 20, 2023
Decision date	Apr 10, 2023
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Changsha Yuwen Medical Equipment Co., Ltd.
Location	Changsha, CN
Contact	Chen Dahui
510(k) history	4 submissions · 4 cleared · 2022-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230164/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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