

K191982 Low-Frequency Multi-function Physiotherapy Instrument (Model: KTR-2230, KTR-2220, KTR-2210, KTR-2231, KTR-2221, KTR-2211, KTR-2232, KTR-2222, KTR-2212)Sep 25, 2020
428 days to decisionK191982 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k191982/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jul 25, 2019
Decision date	Sep 25, 2020
Days to decision	428 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Kentro Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Zewu Zhang
510(k) history	10 submissions · 10 cleared · 2017-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191982/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026