

K200177 Low-frequency Multi-function physiotherapy instrumentMar 25, 2021
426 days to decisionK200177 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k200177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 24, 2020
Decision date	Mar 25, 2021
Days to decision	426 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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