

K231648 Muscle StimulatorMar 1, 2024
270 days to decisionK231648 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k231648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jun 5, 2023
Decision date	Mar 1, 2024
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Yiran Intelligent Co., Ltd.
Location	Shenzhen, CN
Contact	Fengqing Chen
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Huide Medical Technology Service (Shenzhen) Group Co., Ltd.
Contact	Tulin Li

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231648/> 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 13, 2026