

K214100 LuminiceFeb 24, 2022
57 days to decisionK214100 · Product code: **NFO** · Neurology
Source: <https://www.510kdatabase.net/k214100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Dec 29, 2021
Decision date	Feb 24, 2022
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Premier North America, Inc.
Location	Fort Lauderdale, FL, US
Contact	Ellis Tamari
510(k) history	6 submissions · 6 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai CV Technology Co., Ltd.
Contact	Doris Dong

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/k214100/> 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 25, 2026