FDA 510(k) Premarket Notification

K214100 Luminice

CLEARED

Feb 24, 2022
57 days to decision

K214100 · 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