FDA 510(k) Premarket Notification

K251649 Sunny Plus (Sunny)

CLEARED

Sep 18, 2025
112 days to decision

K251649 · Product code: **NFO** · Neurology
Source: https://www.510kdatabase.net/k251649/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	May 29, 2025
Decision date	Sep 18, 2025
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**ShenB Co., Ltd.**
Location	Seongdong-Gu, KR
Contact	Sunny Kang
510(k) history	11 submissions · 11 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**Hoy and Associates Regulatory Consulting**
Contact	Aubrey Thompson

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