FDA 510(k) Premarket Notification

K252187 Aura Glide (FC40)

CLEARED

Dec 23, 2025
162 days to decision

K252187 · Product code: **NFO** · Neurology
Source: https://www.510kdatabase.net/k252187/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Jul 14, 2025
Decision date	Dec 23, 2025
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aura Medical, LLC**
Location	Brooklyn, NY, US
Contact	Connie Lefkowitz
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Gpw Enterprises, LLC**
Contact	Gina Walljasper

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