

**K252187 Aura Glide (FC40)**Dec 23, 2025  
162 days to decisionK252187 · Product code: **NFO** · Neurology  
Source: <https://www.510kdatabase.net/k252187/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Gpw Enterprises, LLC</b>
Contact	Gina Walljasper

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

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