

K250896 Aura WaveDec 2, 2025
252 days to decisionK250896 · Product code: **SGT** · Physical Medicine
Source: <https://www.510kdatabase.net/k250896/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electromagnetic Stimulator For Healthy Muscle Stimulation (SGT)
Date received	Mar 25, 2025
Decision date	Dec 2, 2025
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aura Wellness, LLC
Location	Louisville, KY, US
Contact	Scott Blomberg
510(k) history	2 submissions · 2 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250896/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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