

K220938 Nova HD+Aug 22, 2023
509 days to decisionK220938 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k220938/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Mar 31, 2022
Decision date	Aug 22, 2023
Days to decision	509 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/k220938/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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