FDA 510(k) Premarket Notification

# K220938 Nova HD+

**CLEARED**

Aug 22, 2023
509 days to decision

K220938 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k220938/

## SUBMISSION DETAILS

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|---|---|
| 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 |