

K213748 CoreLeveeOct 14, 2022
318 days to decisionK213748 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k213748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Nov 30, 2021
Decision date	Oct 14, 2022
Days to decision	318 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lutronic Corporation
Location	North Reading, MA, US
Contact	Haewon Park
510(k) history	29 submissions · 29 cleared · 2007-2025

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