

K230261 Gnesis EMS PlusJun 6, 2023
126 days to decisionK230261 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k230261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Jan 31, 2023
Decision date	Jun 6, 2023
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Creative Fitness Developments S.L.
Location	Valencia, ES
Contact	Jose Luis Delgado
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230261/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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