FDA 510(k) Premarket Notification

K212413 I-Motion

CLEARED

May 26, 2022
296 days to decision

K212413 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k212413/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Aug 3, 2021
Decision date	May 26, 2022
Days to decision	296 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**I-Motion Group Global Iberica S.L.**
Location	Alcorcon, ES
Contact	Jose Luis Soto Belloso
510(k) history	1 submissions · 1 cleared · 2022-2022