

**K200545 Legend Pro DMA**Oct 21, 2021  
597 days to decisionK200545 · Product code: **NGX** · Neurology  
Source: <https://www.510kdatabase.net/k200545/>**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 3, 2020
Decision date	Oct 21, 2021
Days to decision	597 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pollogen, Ltd.</b>
Location	Binyamina, IL
Contact	Ayala Kamil
510(k) history	18 submissions · 18 cleared · 2011-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Benjamin L. England and Associates</b>
Contact	Amaya De Levie

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200545/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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