FDA 510(k) Premarket Notification

K200545 Legend Pro DMA

CLEARED

Oct 21, 2021
597 days to decision

K200545 · Product code: **NGX** · Neurology
Source: https://www.510kdatabase.net/k200545/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Benjamin L. England and Associates**
Contact	Amaya De Levie

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