FDA 510(k) Premarket Notification

CLEARED

K191181 NXPRO Neuromuscular Electrical Stimulation Device

Oct 11, 2019
162 days to decision

K191181 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k191181/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	May 2, 2019
Decision date	Oct 11, 2019
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neux Technologies, Inc.**
Location	Tampa, FL, US
Contact	Scot Minniear
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Devine Guidance International, Inc.**
Contact	Christopher J. Devine

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