FDA 510(k) Premarket Notification

K223797 Neuro20 Pro System

CLEARED

Feb 23, 2023
66 days to decision

K223797 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k223797/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Dec 19, 2022
Decision date	Feb 23, 2023
Days to decision	66 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuro20 Technologies**
Location	Tampa, FL, US
Contact	Dennis Schmitt
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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