FDA 510(k) Premarket Notification

K192161 FastFit EMS System

CLEARED

Jan 22, 2020
166 days to decision

K192161 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k192161/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Aug 9, 2019
Decision date	Jan 22, 2020
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fast Fit, LLC**
Location	New York, NY, US
Contact	Lisa Falcone
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Biologics and Medical Device Consulting Group**
Contact	Sigi Caron

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