FDA 510(k) Premarket Notification

K183454 Tyece OTC EMS System

CLEARED

Feb 26, 2019
75 days to decision

K183454 · Product code: **NGX** · Neurology
Source: https://www.510kdatabase.net/k183454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Dec 13, 2018
Decision date	Feb 26, 2019
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Tyece , Ltd.**
Location	Kowloon, HK
Contact	Parshid Falahati
510(k) history	3 submissions · 3 cleared · 2015-2019

REGULATORY CONSULTANT

Consulting firm	**Media Trade Corporation**
Contact	Guenter Ginsberg

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