

**K183454 Tyece OTC EMS System**Feb 26, 2019  
75 days to decisionK183454 · Product code: **NGX** · Neurology  
Source: <https://www.510kdatabase.net/k183454/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Media Trade Corporation</b>
Contact	Guenter Ginsberg

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183454/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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