FDA 510(k) Premarket Notification

K200838 Tyece OTC TENS Model

CLEARED

Aug 12, 2020
134 days to decision

K200838 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k200838/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Mar 31, 2020
Decision date	Aug 12, 2020
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tyece Limited**
Location	Kowloon, CN
Contact	Parshid Falahati
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Mdi Consultants, Inc.**
Contact	Maria Griffin

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