FDA 510(k) Premarket Notification

K193655 MSLS6QF TENS/PMS Device

CLEARED

Sep 4, 2020
249 days to decision

K193655 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k193655/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Dec 30, 2019
Decision date	Sep 4, 2020
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Self Doctor Care, LLC**
Location	Frisco, TX, US
Contact	Wei Wei
510(k) history	1 submissions · 1 cleared · 2020-2020