FDA 510(k) Premarket Notification

K200354 Electronic stimulator

CLEARED

Jun 29, 2020
137 days to decision

K200354 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k200354/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Feb 13, 2020
Decision date	Jun 29, 2020
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Shenzhen Dongjilian Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Zhang Hong
510(k) history	3 submissions · 3 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.**
Contact	Reanny Wang

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