FDA 510(k) Premarket Notification

K192201 Electrical Stimulator System

CLEARED

Jun 12, 2020
304 days to decision

K192201 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k192201/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Aug 13, 2019
Decision date	Jun 12, 2020
Days to decision	304 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gymmax Technology Shenzen Co., Ltd.**
Location	Shenzhen City, CN
Contact	Benson Wang
510(k) history	2 submissions · 2 cleared · 2020-2024