FDA 510(k) Premarket Notification

CLEARED

K213788 TENS&EMS STIMULATOR (Model: KRES100D, KRES1010, KRES1020, KRES1080)

May 6, 2022
151 days to decision

K213788 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k213788/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Dec 6, 2021
Decision date	May 6, 2022
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Dongguan Bohuikang Technology Co.,Ltd**
Location	Dongguan, CN
Contact	Rihua Meng
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Guangdong Jianda Medical Technology Co., Ltd.**
Contact	Jett Lee

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