FDA 510(k) Premarket Notification

CLEARED

K212377 Transcutaneous Electrical Applicator (TEA), Model SNM-FDC01

Apr 15, 2022
256 days to decision

K212377 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k212377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Aug 2, 2021
Decision date	Apr 15, 2022
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Ningbo Medkinetic Medical Device Co., Ltd.**
Location	Ningbo, CN
Contact	Zhang Wei
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

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

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