FDA 510(k) Premarket Notification

CLEARED

K223151 Nu-beca Transcutaneous Electrical Nerve Stimulation

Jul 19, 2023
287 days to decision

K223151 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k223151/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Oct 5, 2022
Decision date	Jul 19, 2023
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nu-Beca & Maxcellent Co.**
Location	Taipei, TW
Contact	David Tsai
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Taidoc Technology Corporation**
Contact	Diana Sung

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