FDA 510(k) Premarket Notification

K220005 TENS & PMS Unit

CLEARED

Apr 1, 2022
87 days to decision

K220005 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k220005/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 4, 2022
Decision date	Apr 1, 2022
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Shenzhen Yuehua Xinsen Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Evin Li
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Guangdong Jianda Medical Technology Co., Ltd.**
Contact	Iris Fung

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