FDA 510(k) Premarket Notification

CLEARED

K220998 Transcutaneous Electrical Nerve Stimulator, Model: KTR-405

Aug 24, 2022
142 days to decision

K220998 · Product code: **NUH** · Physical Medicine
Source: https://www.510kdatabase.net/k220998/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Apr 4, 2022
Decision date	Aug 24, 2022
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Kentro Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Zewu Zhang
510(k) history	10 submissions · 10 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Yvonne Liu

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