FDA 510(k) Premarket Notification

CLEARED

K230782 TENS device-HeadaTerm 2 (Model: YF-HT2)

Feb 26, 2024
341 days to decision

K230782 · Product code: **PCC** · Neurology
Source: https://www.510kdatabase.net/k230782/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	Mar 22, 2023
Decision date	Feb 26, 2024
Days to decision	341 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Wat Medical Technology, Inc.**
Location	Ningbo, CN
Contact	Joe Xu
510(k) history	2 submissions · 2 cleared · 2022-2024