FDA 510(k) Premarket Notification

K233166 NET Recovery Corp/NET Device

CLEARED

May 29, 2024
245 days to decision

K233166 · Product code: **PZR** · Neurology
Source: https://www.510kdatabase.net/k233166/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Nerve Stimulator For Opioid Withdrawal (PZR)
Date received	Sep 27, 2023
Decision date	May 29, 2024
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Net Recovery**
Location	Anaheim Hills, CA, US
Contact	Joe Winston
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J Smith

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

CLINICAL EVIDENCE - NCT04916600

NET Device for Treating Opioid Use Disorder

Status	Active not recruiting
Enrollment	108 patients (actual)
Study sites	1 site
Condition studied	Opioid Use Disorder
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Quadruple
Completion date	Dec 1, 2025
Sponsor	Wayne State University (Other)

Primary outcome

Clinically Meaningful Decrease in Opioid Withdrawal Symptom Severity

Secondary outcome

Comparison of Change in Opioid Withdrawal Symptom Severity Between Active and Sham Device Treatment

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04916600