

K201873 Sparrow Therapy System

Jan 2, 2021
179 days to decisionK201873 · Product code: **PZR** · Neurology
Source: <https://www.510kdatabase.net/k201873/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Nerve Stimulator For Opioid Withdrawal (PZR)
Date received	Jul 7, 2020
Decision date	Jan 2, 2021
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spark Biomedical, Inc.
Location	Dallas, TX, US
Contact	Daniel Powell
510(k) history	3 submissions · 3 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Michelle Rubin-Onur

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

CLINICAL EVIDENCE - NCT04075214

Transcutaneous Auricular Neurostimulation (tAN) for Symptoms of Opioid Withdrawal

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	35 patients (actual)
Study sites	1 site
Condition studied	Opioid-use Disorder; Opioid Withdrawal
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Dec 14, 2020
Sponsor	Spark Biomedical, Inc. (Industry)

Primary outcome

Clinical opiate withdrawal scale (COWS) score

Secondary outcome

Clinical opiate withdrawal scale (COWS) score

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04075214