FDA 510(k) Premarket Notification

K230796 Sparrow Ascent

CLEARED

Jun 20, 2023
90 days to decision

K230796 · Product code: **PZR** · Neurology
Source: https://www.510kdatabase.net/k230796/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Nerve Stimulator For Opioid Withdrawal (PZR)
Date received	Mar 22, 2023
Decision date	Jun 20, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Allison Komiyama

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