FDA 510(k) Premarket Notification

K233162 Freedom Peripheral Nerve Stimulator (PNS) System

CLEARED

Jun 20, 2024
267 days to decision

K233162 · Product code: **GZF** · Neurology
Source: https://www.510kdatabase.net/k233162/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Peripheral Nerve, Implanted (pain Relief) (GZF)
Date received	Sep 27, 2023
Decision date	Jun 20, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Curonix**
Location	Pompano Beach, FL, US
Contact	Hailey Rooney
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Danielle Besal

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

CLINICAL EVIDENCE - NCT02729480

Clinical Trial of Wireless CranioFacial Nerve Stimulation (CFNS) for the Treatment of CranioFacial Neuropathic Pain

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	60 patients (actual)
Study sites	7 sites
Condition studied	Facial Pain
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Oct 1, 2022
Sponsor	Curonix LLC (Industry)

Primary outcome

Pain Score

Secondary outcome

Percentage change from baseline in VAS for facial pain

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02729480