FDA 510(k) Premarket Notification

K221425 Primary Relief

CLEARED

Sep 13, 2022
120 days to decision

K221425 · Product code: **NHI** · Neurology
Source: https://www.510kdatabase.net/k221425/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Percutaneous (pens), For Pain Relief (NHI)
Date received	May 16, 2022
Decision date	Sep 13, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dyansys, Inc.**
Location	Orinda, CA, US
Contact	Srini Nageshwar
510(k) history	14 submissions · 14 cleared · 2007-2022

CLINICAL EVIDENCE - NCT03750357

Percutaneous Electrical Nerve Stimulation (PENS) of the Auricle for Post Operative Pain Solution(POPS) - Cardiac Surgery

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	60 patients (actual)
Study sites	1 site
Condition studied	Post Operative Pain; Midline Sternotomy Incision
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Double blind
Completion date	Dec 17, 2018
Sponsor	DyAnsys, Inc. (Industry)

Primary outcome

PAIN Relief by physical examination by HCP

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03750357