

K220397 ANSiStim-PPMay 12, 2022
90 days to decisionK220397 · Product code: **NHI** · Neurology
Source: <https://www.510kdatabase.net/k220397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Percutaneous (pens), For Pain Relief (NHI)
Date received	Feb 11, 2022
Decision date	May 12, 2022
Days to decision	90 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 - NCT03540446

First Relief Treatment for Peripheral Neuropathy

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	66 patients (actual)
Study sites	1 site
Condition studied	Peripheral Neuropathy
Primary purpose	Treatment
Study type	Interventional
Study design	Factorial
Masking	Double blind
Completion date	Oct 1, 2018
Sponsor	DyAnsys, Inc. (Industry)

Primary outcome

Reduction of Neuropathy pain

Secondary outcome

Check for delay of Re-occurrence of pain within a short time

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03540446
