FDA 510(k) Premarket Notification

K221303 Neuspera Nuity System

CLEARED

Apr 11, 2023
341 days to decision

K221303 · Product code: **GZF** · Neurology
Source: https://www.510kdatabase.net/k221303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Peripheral Nerve, Implanted (pain Relief) (GZF)
Date received	May 5, 2022
Decision date	Apr 11, 2023
Days to decision	341 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuspera Medical, Inc.**
Location	San Jose, CA, US
Contact	Alexander Yeh
510(k) history	2 submissions · 2 cleared · 2021-2023