FDA 510(k) Premarket Notification

K212859 First Relief

CLEARED

Dec 20, 2021
103 days to decision

K212859 · Product code: **NHI** · Neurology
Source: https://www.510kdatabase.net/k212859/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Percutaneous (pens), For Pain Relief (NHI)
Date received	Sep 8, 2021
Decision date	Dec 20, 2021
Days to decision	103 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