FDA 510(k) Premarket Notification

K221210 PainShield MD PLUS

CLEARED

Nov 23, 2022
210 days to decision

K221210 · Product code: **PFW** · Physical Medicine
Source: https://www.510kdatabase.net/k221210/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stationary Ultrasonic Diathermy Device For Use In Applying Therapeutic Deep Heat (PFW)
Date received	Apr 27, 2022
Decision date	Nov 23, 2022
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nanovibronix, Inc.**
Location	Crofton, MD, US
Contact	Hrishikesh Gadagkar
510(k) history	2 submissions · 2 cleared · 2012-2022