

K221210 PainShield MD PLUSNov 23, 2022
210 days to decisionK221210 · Product code: **PFW** · Physical MedicineSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221210/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026