FDA 510(k) Premarket Notification

K232674 PainFreeze II

CLEARED

Feb 12, 2024
164 days to decision

K232674 · Product code: **MLY** · Physical Medicine
Source: https://www.510kdatabase.net/k232674/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vapocoolant Device (MLY)
Date received	Sep 1, 2023
Decision date	Feb 12, 2024
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nuance Medical, LLC**
Location	Carlsbad, CA, US
Contact	Neal Hartman
510(k) history	6 submissions · 6 cleared · 2013-2024