

**K232674 PainFreeze II**Feb 12, 2024  
164 days to decisionK232674 · Product code: **MLY** · Physical MedicineSource: <https://www.510kdatabase.net/k232674/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232674/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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