

**K202993 Buzzy® (models: Mini Healthcare, XL Healthcare, Mini Personal, XL Personal, Pro)**May 15, 2023  
957 days to decisionK202993 · Product code: PHW · Physical Medicine  
Source: <https://www.510kdatabase.net/k202993/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cold Pack And Vibrating Massager (PHW)
Date received	Sep 30, 2020
Decision date	May 15, 2023
Days to decision	957 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VibraCool® (models: Easy Fit, Extended, Plantar, Flex, Pro DME, Pro UE, Pro LE, Pro 200H)

**APPLICANT**

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Company	<b>Mmj Labs, LLC</b>
Location	Atlanta, GA, US
Contact	Amy Baxter
510(k) history	2 submissions · 2 cleared · 2014-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Amy Baxter

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202993/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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