

K202782 num VapocoolantDec 21, 2020
90 days to decisionK202782 · Product code: **MLY** · Physical MedicineSource: <https://www.510kdatabase.net/k202782/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vapocoolant Device (MLY)
Date received	Sep 22, 2020
Decision date	Dec 21, 2020
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	623 Medical, LLC
Location	Morrisville, NC, US
Contact	Ty Schlander
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Gilero, LLC
Contact	James Fentress

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

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