

K203661 CRYO Arctic, CRYO PenguinMay 25, 2022
526 days to decisionK203661 · Product code: **MLY** · Physical MedicineSource: <https://www.510kdatabase.net/k203661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vapocoolant Device (MLY)
Date received	Dec 15, 2020
Decision date	May 25, 2022
Days to decision	526 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cryoscience North America, Inc.
Location	Houston, TX, US
Contact	Greg Nehrlich
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Qpm Consulting, LLC
Contact	Robert Seiple

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203661/> 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