

K242625 Freeze Point & Private Label VersionsOct 25, 2024
52 days to decisionK242625 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Sep 3, 2024
Decision date	Oct 25, 2024
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cryoconcepts LP
Location	Bethlehem, PA, US
Contact	Sam Niedbala
510(k) history	8 submissions · 8 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242625/> 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 13, 2026