

**K211099 Freeze'n Clear Skin Clinic Warts & Tags**Jun 17, 2022  
430 days to decisionK211099 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211099/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Apr 13, 2021
Decision date	Jun 17, 2022
Days to decision	430 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211099/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026