

**K172769 CryOmega Flexx**Nov 30, 2017  
78 days to decisionK172769 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k172769/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Sep 13, 2017
Decision date	Nov 30, 2017
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cryoconcepts LP</b>
Location	Bethlehem, PA, US
Contact	R 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/k172769/> 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