

**K161202 C2 Cryoballoon Ablation System**Jan 5, 2017  
252 days to decisionK161202 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161202/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Apr 28, 2016
Decision date	Jan 5, 2017
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C2 Therapeutics, Inc.</b>
Location	Redwood, Ca, CA, US
Contact	Theresa Brandner-Allen
510(k) history	7 submissions · 7 cleared · 2015-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161202/> 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 31, 2026