

**K131523 CRYOBALLOON FOCAL ABLATION SYSTEM**Aug 22, 2013  
86 days to decisionK131523 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k131523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	May 28, 2013
Decision date	Aug 22, 2013
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C2 Therapeutics</b>
Location	Redwood, Ca, CA, US
Contact	PETER GARCIA-MEZA
510(k) history	3 submissions · 3 cleared · 2010-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131523/> 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 June 4, 2026