

**K161557 truFreeze System**Jul 26, 2016  
50 days to decisionK161557 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161557/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Jun 6, 2016
Decision date	Jul 26, 2016
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CSA Medical, Inc.</b>
Location	Baltimore, MD, US
Contact	SHERRIE COVAL-GOLDSMITH
510(k) history	14 submissions · 14 cleared · 2007-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161557/> 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 15, 2026