

**K253348 TargetCool-e**Oct 15, 2025  
15 days to decisionK253348 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253348/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Sep 30, 2025
Decision date	Oct 15, 2025
Days to decision	15 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Recensmedical, Inc.</b>
Location	Hwaseong-Si, KR
Contact	Minju Choi
510(k) history	7 submissions · 6 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253348/> 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 14, 2026