

**K220674 TargetCool**Mar 31, 2022  
23 days to decisionK220674 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220674/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Mar 8, 2022
Decision date	Mar 31, 2022
Days to decision	23 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	Yeonui Lee
510(k) history	7 submissions · 6 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtechgroup</b>
Contact	Dave Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220674/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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