

K253114 TargetCool™ (RM-DT02W)Oct 16, 2025
22 days to decisionK253114 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Sep 24, 2025
Decision date	Oct 16, 2025
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Recensmedical, Inc.
Location	Hwaseong-Si, KR
Contact	Yeonui Lee
510(k) history	7 submissions · 6 cleared · 2021-2025

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