

K250742 Focused Cryotherapy SystemDec 9, 2025
273 days to decisionK250742 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250742/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Mar 11, 2025
Decision date	Dec 9, 2025
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Focused Cryo, Inc.
Location	Marietta, GA, US
Contact	Yogi Patel
510(k) history	1 submissions · 1 cleared · 2025-2025

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