

**K243042 Co-Ablation System with Sterile Co-Ablation Probe**Jan 29, 2025  
124 days to decisionK243042 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243042/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Sep 27, 2024
Decision date	Jan 29, 2025
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hygea Medical Technology Co., Ltd.</b>
Location	Beijing, CN
Contact	Xingtong Jiang
510(k) history	2 submissions · 2 cleared · 2024-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243042/> 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