

K250852 CoolfaseOct 16, 2025
209 days to decisionK250852 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 21, 2025
Decision date	Oct 16, 2025
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Asterasys Co., Ltd.
Location	Seoul, KR
Contact	Chayeon Kim
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250852/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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