

K242907 DELPHI System

Jun 6, 2025
255 days to decision

K242907 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242907/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 24, 2024
Decision date	Jun 6, 2025
Days to decision	255 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CnS Medical Co., Ltd.
Location	Pocheon-Si, KR
Contact	Lee Jin Wook
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	KMC
Contact	Kim Jiwon

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

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Device record: <https://www.510kdatabase.net/k242907/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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