

K230837 PlazMagikFeb 29, 2024
339 days to decisionK230837 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230837/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 27, 2023
Decision date	Feb 29, 2024
Days to decision	339 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Agnes Medical Co., Ltd.
Location	Seongnam-Si, KR
Contact	Jiwon Kim
510(k) history	7 submissions · 7 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	E & M
Contact	Sanghwa Myung

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

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