

K250217 AGNES Ultra

Sep 3, 2025
222 days to decision

K250217 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250217/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 24, 2025
Decision date	Sep 3, 2025
Days to decision	222 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	Heui Kyeong Pak
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](https://accessdata.fda.gov)
