

**K160469 AGNES**Jan 5, 2017  
321 days to decisionK160469 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160469/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 19, 2016
Decision date	Jan 5, 2017
Days to decision	321 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gwoonsesang Cosmetics Co., Ltd.</b>
Location	Seongnam-Si, KR
Contact	Kyeong Tai Ko
510(k) history	2 submissions · 2 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160469/> 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 June 1, 2026