

**K253165 LAP-iX2N**Jun 9, 2026  
256 days to decisionK253165 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 26, 2025
Decision date	Jun 9, 2026
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sejong Medical Co., Ltd.</b>
Location	Paju-Si, KR
Contact	Jinho Kim
510(k) history	9 submissions · 9 cleared · 2017-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253165/> 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 July 10, 2026