

K200639 LAP-iXSep 29, 2021
568 days to decisionK200639 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200639/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 10, 2020
Decision date	Sep 29, 2021
Days to decision	568 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sejong Medical Co., Ltd.
Location	Paju-Si, KR
Contact	Yoojung Choi
510(k) history	7 submissions · 7 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200639/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026