

K150915 SPINAUT-PMar 18, 2016
347 days to decisionK150915 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k150915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 6, 2015
Decision date	Mar 18, 2016
Days to decision	347 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imedicom Co., Ltd.
Location	Gunpo-Si, KR
Contact	BONGGU HA
510(k) history	6 submissions · 6 cleared · 2016-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150915/> 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 June 28, 2026