

K211000 ACUTRONJun 9, 2022
433 days to decisionK211000 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 2, 2021
Decision date	Jun 9, 2022
Days to decision	433 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ilooda Co.,, Ltd.
Location	Gwonseon-Gu, Suwon-Si, KR
Contact	Yun-Jung Ha
510(k) history	16 submissions · 16 cleared · 2015-2024

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

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/k211000/> 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