

K232223 PlaDuo SystemOct 24, 2023
90 days to decisionK232223 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 26, 2023
Decision date	Oct 24, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ShenB Co., Ltd.
Location	Seongdong-Gu, KR
Contact	Sunny Kang
510(k) history	11 submissions · 11 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	Hoy and Associates Regulatory Consultants
Contact	Aubrey Thompson

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/k232223/> 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 24, 2026