

K251334 NEW DOUBLO 2.0Sep 29, 2025
152 days to decisionK251334 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251334/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 30, 2025
Decision date	Sep 29, 2025
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hironic Co., Ltd.
Location	Gyeonggi-Do, KR
Contact	Lee Gwijin
510(k) history	8 submissions · 8 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251334/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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