FDA 510(k) Premarket Notification

K251334 NEW DOUBLO 2.0

CLEARED

Sep 29, 2025
152 days to decision

K251334 · Product code: **GEI** · General & Plastic Surgery
Source: 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