FDA 510(k) Premarket Notification

K233118 DUET-V (Model: ESK-3261DV)

CLEARED

Jan 3, 2025
464 days to decision

K233118 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233118/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 27, 2023
Decision date	Jan 3, 2025
Days to decision	464 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eunsung Global Corp**
Location	Wonju-Si, KR
Contact	MyeongSoo Woo
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**KMC, Inc.**
Contact	Milly Milly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov