

**K231777 Electrosurgical Generator ESG-410 and Accessories
(WA91327U, WA91327W), Accessories: Foot switches
(WA91311W, WA91321W)**Aug 18, 2023
63 days to decisionK231777 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k231777/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 16, 2023
Decision date	Aug 18, 2023
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Winter & Ibe GmbH
Location	Melville, NY, US
Contact	Ian Pericevic
510(k) history	42 submissions · 42 cleared · 1997-2025

REGULATORY CONSULTANT

Consulting firm	Olympus Surgical Tech. America; Gyrus Acmi, Inc.
Contact	Dolan Mills

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

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