FDA 510(k) Premarket Notification

CLEARED

K203682 Electrosurgical Generator ESG-400, Foot Switches, POWERSEAL Curved Jaw Sealer and Divider, Double Action

May 17, 2021
151 days to decision

K203682 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203682/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 17, 2020
Decision date	May 17, 2021
Days to decision	151 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	Katharina Campbell
510(k) history	42 submissions · 42 cleared · 1997-2025

REGULATORY CONSULTANT

Consulting firm	**Olympus Surgical Technologies America**
Contact	Christina Flores

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